To: Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth

[(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W (b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [na (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Garner, Carl [garner_ (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]

CC: Gonzalez, Nina [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rubin, Daniel B.
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Walker, Paula (NIH/NINDS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
[(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Dana
Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret
Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon
[(b) (6) Stratton, Benjamin [(b) (6)
(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rubin, Daniel B.
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q.
[(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)

CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ronald. (b) (6) Elsaid, Olivia [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Coady, Sean (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5fbec4b18de461888ad57e4eb95303f-coadys]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]

Start: 9/3/2020 5:00:00 PM
End: 9/3/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Butterton, Joan

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; jennifer.j. (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Patterson, Amy (NIH/NHLBI) [E]; Gonzalez, Nina; Punturieri, Antonello (NIH/NHLBI) [E]; Coady, Sean (NIH/NHLBI) [E]

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

Sent: 9/25/2020 5:00:36 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [austinc@mail.nih.gov]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6) Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [(b) (6)]; Erck, Stan [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Lepore, John (b) (6)]; Marks, Peter (FDA/CBER) [Peter.Ma (b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] (b) (6)]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Pandya, Hitesh [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [rachel. (b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6)]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6)]; Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) (b) (6) Victoria Davey [(b) (6) Bancel, Stephane [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Pangalos, Mene [(b) (6) Paul, Steve [(b) (6) Rasi, Guido [(b) (6) Reed, John [(b) (6) Desrosiers, Betsy [(b) (6)

CC: Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen Q. [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6) Mendelson, Jesse (b) (6) Stratton, Benjamin [(b) (6) btolman [(b) (6) Tountas, Karen (FNIH) [T] [ktountas@fnih.org]; Austin, Sarah (NIH/NIAID) [E] [(b) (6)]; Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Bell, Julie [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Trea (NIH) [C] [trea. (b) (6) Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [rhoffstetter@fnih.org]; Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riggin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [donna. (b) (6)]; Sepulveda, Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [dina. (b) (6) Suhana, Tina (NIH/VRC) [E] [(b) (6)]; Thomas, Ashley (FDA/CDER) [(b) (6)]; Wood, Gretchen (NIH/OD) [E] [(b) (6) .gov]; Anderson, James (NIH/OD) [E] (b) (6)]; Burklow, John (NIH/OD) [E] [(b) (6) Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) .com]; FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Myles, Renate (NIH/OD) [E]

[(b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) ; Togashi, Mieko (NIH/NCI) [E]
[(b) (6)]; Underwood, Nancy [(b) (6) Zottoli, Jessica
[(b) (6) Plenge, Robert [(b) (6) Vessey, Rupert [(b) (6)
Regan, Donna M [donna. (b) (6) Sorosa, Alex [(b) (6) Connelly, Sarah
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]; John Lepore
[(b) (6) Grant, Sarah [(b) (6) Qashu, Felicia (NIH/OD) [E]
[(b) (6)]; Wachtel, Jonathan (b) (6) Hamilton, Nancy
[(b) (6)

Subject: ACTIV Leadership Call #10
Attachments: ACTIV Leadership Team Meeting November 19, 2020
Location: https://fnih.zoom.us (b) (6)

Start: 11/19/2020 5:00:00 PM
End: 11/19/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; (b) (6) Davey, Victoria

Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Plenge, Robert; Hamilton, Nancy; Vessey, Rupert; Regan, Donna M; Sorosa, Alex; Connelly, Sarah; Lowy, Douglas (NIH/NCI) [E]; John Lepore; Grant, Sarah; Qashu, Felicia (NIH/OD) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Menon, Sandeep M [(b) (6)
Sent: 5/22/2020 11:43:57 AM
To: Karen Lynn Price [(b) (6) Michael Hughes [(b) (6) LaVange, Lisa M [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; smith.davey [(b) (6) (b) (6) chew.kara [(b) (6) Wohl, David A [(b) (6) Fischer, William A. II [(b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [(b) (6) Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; roa.jhoanna [(b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Elsaid, Olivia [(b) (6) Robert Jan Benschop [(b) (6) Lei Shen [(b) (6)
Subject: Re: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks Karen. It would be tricky to have "informative" prior incorporated as the data is still evolving. I am assuming we will do simulations using "non-informative" priors and incorporate flexibility in the protocol as the data evolves. There are too many variables here – evolving SOC, recruitment rate, correlation between endpoints, etc....

From: Karen Price < (b) (6)
Date: Friday, May 22, 2020 at 12:07 AM
To: Michael Hughes < (b) (6) "LaVange, Lisa M" < (b) (6) "Proschan, Michael (NIH/NIAID) [E]" < (b) (6) "Eron, Joseph J Jr" < (b) (6) "Adam, Stacey (FNIH) [T]" < (b) (6) "currier.judith" < (b) (6) Eric Hughes < (b) (6) Sandeep Menon < (b) (6) "read.sarah" < (b) (6) " (b) (6) < (b) (6) "Rubin, Daniel B. (FDA/CDER)" < (b) (6) "Farley, John (FDA/CDER)" < (b) (6) "smith.davey" < (b) (6) " (b) (6) < (b) (6) "chew.kara" < (b) (6) "Wohl, David A"

< (b) (6) "Fischer, William A. II" < (b) (6) "javan.arzhang" < (b) (6) "Roa, Jhoanna" < (b) (6) " (b) (6) < (b) (6) "kim.peter" < (b) (6) "li.jonathan" < (b) (6) "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" < (b) (6) "Kozak, Marina (OS/ASPR/BARDA)" < (b) (6)
Cc: "DeMarcus, Forrest" < (b) (6) "Tountas, Karen (FNIH) [T]" < (b) (6) "Wachtel, Jonathan" < (b) (6) Elizabeth Kim < (b) (6) "Parker, Ashley (NIH/OD) [E]" < (b) (6) "roa.jhoanna" < (b) (6) "Smith, David" < (b) (6) Paul Klekotka < (b) (6) Ajay Nirula < (b) (6) "Elsaid, Olivia" < (b) (6) Robert Jan Benschop < (b) (6) Lei Shen < (b) (6)
Subject: Re: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks Lisa and Michael.
Working now to put together more details on the modeling and developing a simulation plan. We look forward to discussing in our stats meetings soon. Whether we end up with Bayesian or frequentist approach, simulation of this design will be required in order to better understand the operating characteristics.

I do think it is important we keep in mind that for a master protocol such as this, the specific model used and associated priors will necessarily change over time. So the intent would be to put the basic framework of the model into the master protocol, but specify the model, agent's specific sample size, and operating characteristics assessed via simulation in the associated agent's appendix. One advantage of this is that in order to navigate through these many agents efficiently and effectively we necessarily need to learn over time and formally incorporate that learning into our modeling. For example, we will learn more over time about the relationship between the symptomatic endpoints/viral endpoints/clinical endpoint (hospitalization/er visit/death) and that learning needs to be incorporated into future agent's modeling, which should also lower sample size and improve precision/decision making across these agents. It is presently unclear to me how we can effectively evaluate several agents / borrow placebo / incorporate prior knowledge we will gain over time / etc without a Bayes approach, but I look forward to discussing in our stats meetings.

Thanks,
Karen

From: Michael Hughes < (b) (6)
Date: Thursday, May 21, 2020 at 12:54 PM
To: "LaVange, Lisa M" < (b) (6) "Proschan, Michael (NIH/NIAID) [E]" < (b) (6) "Eron, Joseph J Jr" < (b) (6) "Adam, Stacey (FNIH) [T]" < (b) (6) "currier.judith" < (b) (6) Eric Hughes < (b) (6) Sandeep Menon < (b) (6) "read.sarah" < (b) (6) "Price, Dionne (FDA/CDER)" < (b) (6) "Rubin, Daniel B. (FDA/CDER)" < (b) (6) "Farley, John (FDA/CDER)" < (b) (6) Karen Price < (b) (6) "smith.davey" < (b) (6) " (b) (6) < (b) (6) "chew.kara" < (b) (6) "Wohl, David A" < (b) (6) "Fischer, William A. II" < (b) (6) "javan.arzhang" < (b) (6) "Roa, Jhoanna" < (b) (6) " (b) (6) < (b) (6) "kim.peter" < (b) (6) "li.jonathan" < (b) (6) "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" < (b) (6) "Kozak, Marina (OS/ASPR/BARDA)" < (b) (6)
Cc: "DeMarcus, Forrest" < (b) (6) "Tountas, Karen (FNIH) [T]" < (b) (6) "Wachtel, Jonathan" < (b) (6) Elizabeth Kim < (b) (6) "Parker, Ashley (NIH/OD) [E]" < (b) (6) "roa.jhoanna" < (b) (6) "Smith, David"

< (b) (6) Paul Klekotka < (b) (6) Ajay Nirula < (b) (6)
"Elsaid, Olivia" < (b) (6) Robert Jan Benschop < (b) (6) Lei Shen
< (b) (6)
Subject: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

Hi Lisa,

That's fine. Perhaps you and Karen could circulate some brief details of the Bayesian model framework and associated priors for each outcome measure you are envisaging? --- I think that would help in moving things along.

Looking forward to discussing,

Michael

From: LaVange, Lisa M <lisa. (b) (6)
Sent: Thursday, May 21, 2020 1:34 PM
To: Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; (b) (6) chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; (b) (6) kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

From: Michael Hughes [mailto: (b) (6)
Sent: Thursday, May 21, 2020 11:03 AM
To: Proschan, Michael (NIH/NIAID) [E] < (b) (6) LaVange, Lisa M < (b) (6) Eron, Joseph J Jr < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) currier.judith < (b) (6) Eric Hughes < (b) (6) Sandeep Menon < (b) (6) read.sarah < (b) (6) Price, Dionne (FDA/CDER) < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price < (b) (6) smith.davey < (b) (6) (b) (6) chew.kara < (b) (6) Wohl, David A <david_ (b) (6) Fischer, William A. II <william_ (b) (6) javan.arzhang < (b) (6) Roa, Jhoanna < (b) (6) (b) (6) kim.peter < (b) (6) li.jonathan < (b) (6) Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA) < (b) (6)
Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) roa.jhoanna < (b) (6) Smith, David < (b) (6) Paul Klekotka < (b) (6) Ajay Nirula < (b) (6) Elsaid, Olivia < (b) (6) Robert Jan Benschop <benschop_ (b) (6) Lei Shen < (b) (6)
Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at >=50% enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks,

Michael

From: Proschan, Michael (NIH/NIAID) [E] < (b) (6)
Sent: Thursday, May 21, 2020 8:52 AM
To: LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; Michael Hughes; (b) (6) chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; (b) (6) ; kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

From: LaVange, Lisa M < (b) (6)
Sent: Thursday, May 21, 2020 7:53 AM
To: Eron, Joseph J Jr (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Judy Currier < (b) (6) Eric Hughes (b) (6) >; Sandeep Menon < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) >; Price, Dionne (FDA/CDER) (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) v>; Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price (b) (6) (b) (6) (b) (6) (b) (6) Wohl, David A (b) (6) Fischer, William A. II (b) (6) Javan, Arzhang (NIH/NIAID) [E] (b) (6) Roa, Jhoanna (b) (6) Kim, Peter (NIH/NIAID) [E] <p (b) (6) ; Jonathan Li (b) (6) ; Marks, Gilbert (OS/ASPR/BARDA) (CTR) (b) (6) ; Kozak, Marina (OS/ASPR/BARDA) < (b) (6)
Cc: DeMarcus, Forrest (b) (6) >; Tountas, Karen (FNIH) [T] (b) (6) Wachtel, Jonathan (b) (6) ; Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Jhoanna Roa (b) (6) ; Smith, David (b) (6) Paul Klekotka (b) (6) Ajay Nirula (b) (6) Elsaid, Olivia < (b) (6) Robert Jan Benschop (b) (6) Lei Shen (b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.

Lisa

From: Eron, Joseph J Jr
Sent: Wednesday, May 20, 2020 6:23 PM
To: Adam, Stacey (FNIH) [T] (b) (6) ; Judy Currier < (b) (6) Eric Hughes (b) (6) ; LaVange, Lisa M < (b) (6) Sandeep Menon < (b) (6) Proschan, Michael (NIH/NIAID) [E] (b) (6) v>; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Price, Dionne (FDA/CDER) < (b) (6) v>; Rubin, Daniel B. (FDA/CDER) (b) (6) >; Farley, John (FDA/CDER) (b) (6) ; Karen Lynn Price (b) (6) (b) (6) (b) (6) kchew@mednet.ucla.edu; Wohl, David A (b) (6) >; Fischer, William A. II (b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna < (b) (6) (b) (6) Kim, Peter

(NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6) Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA) (b) (6)
Cc: DeMarcus, Forrest (b) (6) Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan < (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka (b) (6) Ajay Nirula (b) (6) >; Elsaid, Olivia (b) (6) >; Robert Jan Benschop (b) (6) >; Lei Shen (b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim "activity" analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD

Professor of Medicine

University of North Carolina at Chapel Hill

School of Medicine

(b) (6)

From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Wednesday, May 20, 2020 5:42 PM
To: Judy Currier < (b) (6) Eric Hughes < (b) (6) LaVange, Lisa M (b) (6) ; Sandeep Menon < (b) (6) Proschan, Michael (NIH/NIAID) [E] (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER) (b) (6) Rubin, Daniel B. (FDA/CDER) (b) (6)

Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price (b) (6)
(b) (6) (b) (6) (b) (6)
Wohl, David A (b) (6) >; Fischer, William A. II < (b) (6) Eron, Joseph J Jr (b) (6) >; Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6) Kim, Peter (NIH/NIAID) [E] (b) (6) ; Jonathan Li < (b) (6) Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA) < (b) (6)
Cc: DeMarcus, Forrest (b) (6) >; Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan (b) (6) >; Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) >; Jhoanna Roa < (b) (6) Eron, Joseph J Jr (b) (6) Smith, David < (b) (6) Paul Klekotka (b) (6) Ajay Nirula (b) (6) ; Elsaid, Olivia (b) (6) Robert Jan Benschop (b) (6) Lei Shen (b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 5/21/2020 8:24:18 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

No, so thanks for sending. I will request Stacey and Mike to add me to the Therapeutics Clinical and Vaccine WG calls. Do you want to chat this evening or tomorrow morning?

From: Gadbois, Ellen (NIH/OD) [E] < (b) (6)
Sent: Thursday, May 21, 2020 4:01 PM
To: Culp, Michelle (NIH/OD) [E] < (b) (6)
Subject: FW: Slides for ACTIV TX-Clinical Working Group Meeting #7

Did you get this in time to join today? I did. You should try to follow this group. They mostly talked about their plans for a master protocol for the mAbs and I'm sure you would get more out of the details. But I have some observations (not urgent to discuss).

From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Thursday, May 21, 2020 12:44 PM
To: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) Butterton, Joan <joan (b) (6) De Claro, R. Angelo (FDA/CDER) < (b) (6) Draghia-Akli, Ruxandra < (b) (6) Eisner, Mark < (b) (6) Gottesdiener, Keith < (b) (6) Hughes, Eric < (b) (6) Judy Currier < (b) (6) Kim, Elizabeth < (b) (6) LaVange, Lisa < (b) (6) Levy, Elliot < (b) (6) Mellors, John W < (b) (6) Menon, Sandeep < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Patel, Naimish < (b) (6) Peppercorn, Amanda < (b) (6) Poole, Mike < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen, Yuan Li (FDA/CDER) < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) Collins, Sylva (FDA/CDER) <Sylva.Co (b) (6) Amanda Peppercorn < (b) (6) Garner, Carl <garner_carlos (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) Burgess, Timothy < (b) (6) Reineck, Lora (NIH/NHLBI) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6)
Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy <elizabeth (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Young, John < (b) (6) Biggs, Mary < (b) (6) Butcher, Tina <tina (b) (6) Demarcus < (b) (6) Macone, Erin < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Salathin, Carla < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6) Tolman, Brett < (b) (6) Alvarez, Rosa < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio < (b) (6) Rose Li Central Account < (b) (6) Anderson, Margaret < (b) (6) Lucas Smalldon < (b) (6) Stratton, Benjamin < (b) (6) (b) (6) Mollica, Linda /US < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Patterson, Amy (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]

< (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6)
Subject: Slides for ACTIV TX-Clinical Working Group Meeting #7

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Mellors, John W (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Jacqueline Kirchner [(b) (6) Garner, Carl [(b) (6) Menon, Sandeep [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [keith. (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier

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[(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6)

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[john. (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
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(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Dana
Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret
Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon
[(b) (6) Stratton, Benjamin [(b) (6)
(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
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(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US
[(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6)

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200723.pdf

Start: 7/23/2020 5:00:00 PM
End: 7/23/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Jacqueline Kirchner; Garner, Carl; Menon, Sandeep; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)

Dear ACTIV TX-Clinical WG members,

Please find attached the slides for today's meeting with the agenda.
We will have a speaker from NIAID presenting on a new master protocol idea.

Thanks,
Stacey

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CC: (b) (6) K C Kent Lloyd [(b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; antoinette_baric

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Start: 10/21/2020 2:15:00 PM
End: 10/21/2020 3:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Required Attendees: (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) .gov; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Optional Attendees: (b) (6) (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/17/2020 11:57:01 AM
To: Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) .com]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)
CC: Elizabeth Kim [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6) Salathin, Carla (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)
Subject: Canceling Agent Prioritization Subgroup Meeting Today (Thank you for the homwork!)

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Thank you to all of you who sent in your responses on the criteria and your willingness to participate in the agent prioritization effort. We got 80% of the group, so we will be cancelling today's meeting to allow the co-chairs to review and compile the feedback.

However, you are not completely off the hook. Be on the lookout for materials later today that we will ask you to review over the weekend and come prepared to discuss on Monday and Tuesday.

Thank you all for all you time and efforts this week! We look forward to seeing you again next week ready to keep pushing forward!

Kind regards,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

-----Original Appointment-----
From: Adam, Stacey (FNIH) [T]
Sent: Thursday, April 16, 2020 4:52 PM
To: Adam, Stacey (FNIH) [T]; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim

(OS/ASPR/BARDA) (CTR); Vincent, Michael
Cc: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon
Subject: HOLD for Potential Agent Prioritization Subgroup
When: Friday, April 17, 2020 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Zoom TBD

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Thank you to all of you who sent in your responses on the criteria and your willingness to participate in the agent prioritization effort. We got 80% of the group, so we will be cancelling today's meeting to allow the co-chairs to review and compile the feedback.

However, you are not completely off the hook. Be on the look out for materials later today that we will ask you to review over the weekend and come prepared to discuss on Monday and Tuesday.

Thank you all for all you time and efforts this week! We look forward to seeing you again next week ready to keep pushing forward!

Kind regards,
Stacey

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/18/2020 8:31:14 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [(b) (6) Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Pao, William [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John (b) (6) Freire, Maria (FNIH) [T] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) Anderson, James (NIH/OD) [E] (b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Marks, Peter (FDA/CBER) [(b) (6)]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Elsaid, Olivia [(b) (6) Gonzalez, Nina [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Kim, Elizabeth [(b) (6)]; Menetski, Joseph (FNIH) [T] (b) (6) Santos, Michael (FNIH) [T] [(b) (6) Stratton, Ben [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan (b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] (b) (6) ; Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; McManus, Ayanna (NIH/OD) [E] [(b) (6) Protasiewicz, Ann [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6)]; Wood, Gretchen (NIH/OD) [E] [(b) (6) Zanellato, Ann [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Li, Rose [(b) (6) FNIH Central Account [(b) (6) Awwad, David (NIH/NIAID) [C] [(b) (6) Zottoli, Jessica [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6)]; Sepulveda, Dorina (FNIH) [T] [(b) (6) Hardesty, Rebecca (NIH/OD) [C] [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Carver, Trea (NIH) [C] [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) (b) (6)

Subject: ACTIV Executive Committee Teleconference
Location: https://fnih.zoom. (b) (6)

Start: 5/20/2020 7:30:00 PM
End: 5/20/2020 9:00:00 PM
Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Freire, Maria (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Anderson, James (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Marks, Peter (FDA/CBER)
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Kim, Elizabeth; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood,

Gretchen (NIH/OD) [E]; Zanellato, Ann; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Li, Rose; FNIH Central Account; Awwad, David (NIH/NIAID) [C]; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Hardesty, Rebecca (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; Carver, Trea (NIH) [C]; Lowy, Douglas (NIH/NCI) [E]; (b) (6)

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US (San Jose)
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US (Houston)
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/9/2020 2:52:29 AM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) ; Eron, Joe (b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; LH (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6) Eron, Joseph J Jr (b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Chen, Helen Q. [(b) (6)

Subject: HOLD for Potential ACTIV-2 Writing Team Meeting
Location: https://fnih.zoom.us/j/ (b) (6)

Start: 6/11/2020 2:00:00 PM
End: 6/11/2020 3:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) (b) (6) edaa (b) (6) (b) (6) (b) (6) (b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/22/2020 1:58:32 AM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6)

CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US (b) (6)

Subject: Follow-up from ACTIV TX-Clinical Master Protocol Subgroup Meeting #4

Attachments: D. Goff network capacity template_04202020.xlsx; 2020-04-20_TX-Clinical_WG_Master_Protocols_Subgroup_Summaryv2.pdf; Platform Trial Statistical Issue Considerations.pdf; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 4_Key Takeaways_04212020_v2.pdf; BET synopsis v0.2 - 15Apr2020 DRAFT.pdf

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Thank you once again for a productive session today. We have another meeting on the books tomorrow, and you will see ones for Thursday, Friday and a weekend day, as soon as I have had a chance to discuss with the co-chairs. We appreciate you all being willing to commit the extra time to help us ensure we meet our aggressive timelines.

Please find attached the follow up materials from today's meeting.

1. The Formal Summary of yesterday's subgroup meeting.
2. The high level summary and action items from today's subgroup meeting.
3. The Clinical Trial Capacity WG network capacity for your review. This will let you know what data they are collecting to help us determine who is equipped to run the de novo master protocol.
4. The BET Protocol for this group's review. We would ask that you not distribute beyond this group as this protocol is still in DRAFT form. This is for consideration for the de novo master protocol discussion. This protocol has not yet been submitted for review.
5. Mike Proschan's statistical considerations for the group's review.

We will send the materials for tomorrow shortly, as it will be a new agenda, but the slides from today, so we can spend more time going through Lisa's consideration categories.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 6/30/2020 3:07:29 AM

To: Jim Neaton [(b) (6) Jens Lundgren [jens.l (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Srinivasan, Badhri (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; wesley.self@vumc.org; Gelijns, Annetine (b) (6) ; Mark Polizzotto [(b) (6) Ginny Kan [(b) (6) Baker, Jason [(b) (6) Roger Paredes [(b) (6) Thompson, Taylor,M.D. (b) (6) Babiker, Ab [a. (b) (6) Ginde, Adit [(b) (6) Aileen M Ilaria [(b) (6) Ringwood, Nancy J [(b) (6) Oldmixon, Cathryn F. [(b) (6)

CC: Kenny, Dermot [(b) (6) Baseler, Beth (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2363525c118a468b9e8f5f61707c63f5-bbaseler]; Chen, Helen Q. [(b) (6) Wachtel, Jonathan [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pett, Sarah [(b) (6) Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrettk2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccbr]; Eileen Denning [(b) (6) Engel, Theresa (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e86305ea82754e65b67a63591ed867ba-engelt]; Lisbeth Jørgensen [(b) (6) RH-FP-INSIGHT014-ACTIV3 [(b) (6)

Erhardt, William (HHS/IOS) [(b) (6) Judith Anne Gallagher (b) (6) Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]

Subject: ACTIV-3 Operations Team Meeting
Attachments: ACTIV_TX-Clinical_ACTIV-3 Operations Team Meeting Agenda_20200630.docx
Location: https://fnih.zoom. (b) (6)

Start: 6/30/2020 3:00:00 PM
End: 6/30/2020 4:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday from 11:00 AM to 12:00 PM
Required Attendees: Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (HHS/IOS); Reineck, Lora (NIH/NHLBI) [E]; (b) (6) Gelijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor,M.D.; Babiker, Ab; Ginde, Adit; Aileen M Ilaria; Ringwood, Nancy J; Oldmixon, Cathryn F.
Optional Attendees: Kenny, Dermot; Baseler, Beth (NIH) [C]; Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen; Eileen Denning; Engel, Theresa (NIH) [C]; Lisbeth Jørgensen; RH-FP-INSIGHT014-ACTIV3; Erhardt, William (HHS/IOS); Judith Anne Gallagher; Harrigan, Rachel (HHS/IOS)

Dear ACTIV-3 Operations Team,

I will let Jim, Libby, and Laura weigh in further, but here is a basic high level agenda for tomorrow.
I look forward to chatting with you all then. Jim, send me any slides you would like to have me present.

Thanks,
Stacey

Meeting: 11am-12pm ET

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6)]; Prabhavathi

Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) (b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [(b) (6) (b) (6)

Subject: Canceled: ACTIV Preclinical full working group

Start: 12/30/2020 3:00:00 PM
End: 12/30/2020 4:00:00 PM
Show Time As: Free

Recurrence: (none)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 10/1/2020 4:44:54 PM

To: Levy, Elliot [(b) (6) Jacqueline Kirchner [(b) (6) Garner, Carl [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201001_vF.pdf
Location: https://fnih.zoom. (b) (6)

Start: 10/1/2020 5:00:00 PM
End: 10/1/2020 6:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Levy, Elliot; Jacqueline Kirchner; Garner, Carl; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Merritt, Gabriella Marie; Margaret Anderson; Gonzalez, Nina; Kurilla, Michael (NIH/NCATS) [E]; (b) (6) Stock, Thomas (HHS/IOS); Freire, Maria (FNIH) [T]; Desrosiers, Betsy; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's presentation.

Thanks,
Stacey

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CC: Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; caroline.sferrazza@roseliassociates.com; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; (b) (6) Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; 'Jansen, Kathrin' [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]

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Subject: RE: ACTIV Preclinical full working group

Attachments: The Problem of 'Long Haul' COVID - Scientific American.pdf

Dear All,

The problem is getting good lay press. I got this from Scientific American!

Regards,

Prabha

From: Fessel, Josh (NIH/NHLBI) [E] < (b) (6)

Sent: Wednesday, January 13, 2021 11:54 AM

To: Menetski, Joseph (FNIH) [T] < (b) (6) (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] < (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph < (b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Hewitt, Judith (NIH/NIAID) [E] < (b) (6) Deming, Damon (FDA/CDER) < (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA) < (b) (6) Rao, Srinivas < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar

< (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) < (b) (6)
Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Charette, Marc (NIH/NHLBI) [E]
< (b) (6) (b) (6)
Cc: Hawk, Harrison < (b) (6) (b) (6) Gonzalez, Nina
< (b) (6) (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Simon,
Dina (NIH/OD) [C] < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Austin, Christopher
(NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Colvis, Christine
(NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy < (b) (6) Eric Hughes
< (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]
< (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)
Tountas, Karen (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T]
< (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria < (b) (6)
Kim, Elizabeth < (b) (6) btolman < (b) (6) Wachtel, Jonathan < (b) (6)
Prabhavathi Fernandes < (b) (6) Diamond, Michael < (b) (6) Rose Li
< (b) (6) Dana Carluccio < (b) (6) Lagos, Enrique (NIH/NCATS) [E]
< (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Burrus-Shaw, Cyndi
(NIH/OD) [E] < (b) (6) Rodriguez, Robin D < (b) (6) Dave Frankowski
< (b) (6) antoinette_baric < (b) (6) Lowy, Douglas
(NIH/NCI) [E] < (b) (6) Nancy Haigwood < (b) (6) Stratton, Benjamin
< (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E]
< (b) (6) Mason, Stephen < (b) (6) Connelly, Sarah
< (b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C] < (b) (6) K C Kent
Lloyd < (b) (6)
Subject: RE: ACTIV Preclinical full working group

Hi everyone,

Joe, thanks for sharing! This article is getting a lot of attention, and understandably so. There's a nice Commentary that accompanied it, and I'm attaching that as well. Prabha, thanks for sharing the article you shared as well!

The study like this one that's been on my mind is the attached preprint from medRxiv. It's a patient-led research effort (from the group that was in attendance at the recent trans-NIH workshop on Post-Acute Sequelae of COVID, hosted by NIAID), which I think some might see as a negative (consciously or unconsciously). For me, that's one of its chief strengths. Long COVID is at present a symptom-defined syndrome, and the patients are our best teachers. Though the study reported in the medRxiv manuscript is by no means perfect, I've found it to be very informative.

Thanks so much, everyone!

All my best,

Josh

Josh Fessel, MD, PhD

Pronouns: he/him/his
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Division of Lung Diseases | National Heart, Lung, and Blood Institute
National Institutes of Health
6705 Rockledge Drive | Room 405-F, MSC 7952 | Bethesda, MD 20892-7952
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From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Wednesday, January 13, 2021 10:55 AM
To: ; (b) ; Hild, Sheri (NIH/OD) [E] (b) (6) (b) (6) (b) (6) Baric, Ralph (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] (b) (6) >; Colvis, Christine (NIH/NCATS) [E] (b) (6) ; Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) (b) (6) ; (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) Collins, Francis (NIH/OD) [E] (b) (6) ; ; Adams, Peter (OS/ASPR/BARDA) (b) (6) ; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] (b) (6) Tomas Cihlar (b) (6) >; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) ; Punturieri, Antonello (NIH/NHLBI) [E] (b) (6) ; Charette, Marc (NIH/NHLBI) [E] (b) (6) ; Fessel, Josh (NIH/NHLBI) [E] (b) (6) ; (b) (6) ;
Cc: Hawk, Harrison (b) (6) Gonzalez, Nina (b) (6) Florence, Clint (NIH/NIAID) [E] (b) (6) >; Simon, Dina (NIH/OD) [C] < (b) (6) ; Wholley, David (FNIH) [T] < (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) >; Colvis, Christine (NIH/NCATS) [E] (b) (6) ; Desrosiers, Betsy (b) (6) >; Eric Hughes (b) (6) ; Jansen, Kathrin (b) (6) ; Kurilla, Michael (NIH/NCATS) [E] (b) (6) ; Lowy, Douglas (NCI) (b) (6) ; Read, Sarah (NIH/NIAID) [E] < (b) (6) ; Tountas, Karen (FNIH) [T] (b) (6) ; Santos, Michael (FNIH) [T] (b) (6) ; Adam, Stacey (FNIH) [T] (b) (6) James, Stephanie (FNIH) [T] (b) (6) ; Alvarez, Rosa Maria (b) (6) ; Kim, Elizabeth (b) (6) >; btolman (b) (6) ; Wachtel, Jonathan (b) (6) ; Prabhavathi Fernandes (b) (6) ; Diamond, Michael (b) (6) ; Rose Li (b) (6) ; Dana Carluccio (b) Lagos, Enrique (NIH/NCATS) [E] < (b) (6) ; Jonson, Samantha (NIH/NCATS) [E] (b) (6) >; Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6)) (6) ; Rodriguez, Robin D < (b) (6) ; Dave Frankowski (b) (6) ; antoinette_baric (b) (6) ; Lowy, Douglas (NIH/NCI) [E] (b) (6) ; Nancy Haigwood (b) (6) ; Stratton, Benjamin < (b) (6) ; Gadbois, Ellen (NIH/OD) [E] < (b) (6) ; Anderson, James (NIH/OD) [E] (b) (6) Mason, Stephen (b) (6) Connelly, Sarah < (b) (6) Lumsden, Joanne (NIH/NCATS) [C] (b) (6) ; K C Kent Lloyd (b) (6)
Subject: RE: ACTIV Preclinical full working group

Dear all,

Thought you might be interested in this article on COVID-19 sequalae.

Does anyone know of other reports like this? It could be important to incorporate this in our thoughts for therapeutics going forward.

Best regards,
Joe

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterton, Joan [(b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6) Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [(b) (6)]; Judy Currier [(b) (6) Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [(b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6) Collins, Sylva (FDA/CDER) [(b) (6)]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [(b) (6) Timothy Burgess [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [(b) (6)]; Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6) Goff, David (NIH/NHLBI) [E] (b) (6)]; Brown, Jeremy (NIH/NINDS) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6)]; Culp, Michelle (NIH/OD) [E] [(b) (6) Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [(b) (6) Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [(b) (6) Garner, Carl [(b) (6)

CC: Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [(b) (6) Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Salathin, Carla [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [felicia. (b) (6) Patterson, Amy (NIH/NHLBI) [E] [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [(b) (6) Groesch, Mary (NIH/NHLBI) [E] [(b) (6) Shipp, Allan (NIH/NHLBI) [E] (b) (6) ; Kindzelski, Andrei (NIH/NHLBI) [E (b) (6)]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Walker, Paula (NIH/NINDS) [E] [(b) (6) Sorosa, Alex David [(b) (6) Lumsden, Joanne (NIH/NCATS) [C] [(b) (6)

Start: 1/14/2021 6:00:00 PM
End: 1/14/2021 7:00:00 PM

Recurrence: (none)

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/9/2020 12:21:37 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: GSK follow up on FNIH COVID call

I'll do it.

From: Wholley, David (FNIH) [T] < (b) (6)
Sent: Wednesday, April 8, 2020 7:36 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Erbelding, Emily (NIH/NIAID) [E] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6)
Subject: FW: GSK follow up on FNIH COVID call

FYI We'll add them to the list. Francis, do you want to send out the invitation emails? We can forward yours if you don't have time.

From: John Lepore (b) (6)
Sent: Wednesday, April 8, 2020 5:55 PM
To: Wholley, David (FNIH) [T] < (b) (6)
Cc: Santos, Michael (FNIH) [T] (b) (6) >; David Payne (b) (6) Emmanuel Hanon (b) (6) Amanda Peppercorn (b) (6)
Subject: RE: GSK follow up on FNIH COVID call

Hi David -

Writing e-mail to you as I received this...

Yes, we are very keen to participate with the following suggestions:

- **David Payne**, head of our infectious disease research group, to participate on the preclinical workstream. David is an industry veteran with extensive drug discovery experience across novel anti-bacterials and anti-virals and I think can contribute importantly to discussions about optimizing assays, reagents and models.
- **Amanda Peppercorn**, physician-scientist with extensive experience in clinical trials and and regulatory interactions for anti-viral drug-development; has led our influenza program, among others. To participate on the clinical trials workstream.

- **Emmanuel Hanon** - head of vaccines R&D in GSK, to participate on the vaccines workstream.

I've copied all 3 on this e-mail so you can contact them directly.

If you would please keep me copied in to minutes from the various workstreams, I'd really appreciate that.

If there is anything else GSK could help with, please do reach out.

Thanks so much for your help -

John

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Wednesday, April 08, 2020 5:48 PM
To: John Lepore (b) (6)
Cc: Santos, Michael (FNIH) [T] (b) (6)
Subject: RE: GSK follow up on FNIH COVID call

EXTERNAL

Hi John, I don't think I have seen your suggestions for the COVID committees yet, just checking. We'd love to have input from your leadership, particularly on vaccines and therapeutics groups. Thanks, David

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/28/2020 3:17:27 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: Agent Prioritization Committee and Process

Hi Larry,
As I mentioned, the prioritization process has morphed somewhat as the group examined the kind of data they were getting and wrangled the details of how best to do this a little more. Please let me know if you would like to discuss and I can pull together another call with Stacey Adam, Joe Menetski and whomever you wish to attend from your side. Thanks, David

---

From: Wholley, David (FNIH) [T]
Sent: Tuesday, April 28, 2020 11:02 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6)
Subject: Agent Prioritization Committee and Process

Hi Francis,
As requested on this morning's call here is the membership of the Agent Prioritization Sub Group of the Therapeutics-Clinical WG and a summary of the approach they are taking to prioritize agents for testing in ACTIV. As I mentioned and is indicated below, relevant MOA is a primary criterion for initial sorting of candidates. Please let me know if you have additional questions regarding this. David

Main Review Committee

- Eric Hughes – Novartis
- Sarah Read - NIAID
- Timothy Buchman - BARDA
- Ruxandra Draghia Akli – J&J
- Keith Gottesdiener – COVID-19 R&D Leaders Consortium
- Elliott Levy - Amgen
- John Mellors – U. Pittsburgh
- Naimish Patel - Sanofi
- Mike Vincent – Pfizer (member of Clinical Trials WG)
- Peter Wung – Sanofi and JHU
- John Young - Roche
- Christine Colvis - NCATS
- Libby Higgs - NIAID

Tie-breaker Reviewer (if needed)

- Walter Koroshetz - NINDS

Strategic Guidance (Non-Voting)

- Peter Stein – FDA (CDER)
- Mike Poole – BMGF (Therapeutics Accelerator Lead)

Current Process
The current agent prioritization process is a multistage process.

1. Step 1: The FNIH team and the co-chairs divided the original list of agents pulled from publicly accessible data (~400 compounds) "Wave Groups" via their stage in development, i.e. FDA-approved/IND-enabled, Clinically ready, Preclinical.
2. Step 2: The Main Review Committee is currently triaging the list of agents that were FDA-approved/IND-enabled or strongly clinical ready and that were grouped by Mechanisms of Actions (MOA) (~170 agents) to quickly evaluate relevant MOAs, perceived best in class for most relevant MOAs, and thereby whittle down agents for use in the first master protocol planned. The "repurposed" master protocol which is imagined to be a larger Phase III trial of at least 3 agents ready for this stage. Each compound is being assessed for triage by two reviewers.
3. Step 3: The Main Review Committee will meet to adjudicate or have the tie-breaker reviewer decided on any agents where the first two reviewers disagree on the triage status.
4. Step 4: Any agents that make it through the triage process (likely ~30-40 agents) will be scored by each of the Main Review Committee members individually (per Larry Tabak's request) via the Agent Prioritization Scoring Criteria that was selected by the group, and based on data that is available in the public domain. This will happen between Tuesday night to Thursday afternoon this week of the process continues on pace.

Agent Prioritization Criteria for Wave 1

Rationale for MOA to be relevant to COVID-19	SARS-CoV2 Trials	Preclinical data (SARS-COV2)	PK/PD	Safety	Drug-Drug Interactions	Availability/Scalability
Strong (2)	Data from one or more small RCTs (3)	In vivo data in appropriate animal model (3)	Sufficient plasma and tissue(lung) levels (3)	No concerns (3)	None (1)	Already sufficient drug in stock to begin large trials (3)
Weak (1)	Data from one or more uncontrolled trials (2)	In vitro viral inhibition data in multiple relevant cell lines (2)	Sufficient plasma levels (2)	Minor concerns (1-2)	Clinically Significant DDIs (0)	Drug in stock with ability to manufacture enough for trial in short timeframe (2)
None (No Go)	Case series, anecdotal data (1)	In vitro suggestive mechanism data (1)	Insufficient data to judge (0)	Insufficient data to judge 0)		Manufacturing capabilities available, but not ramped up (1)
	None (0)	None (0)	Insufficient levels (No Go)	Major concern (No Go)		Not scalable at this time (No Go)

5. Step 5: The FNIH/Deloitte Team will compile and average the scores for this agents and create a rank priority list.
6. Step 6: The Agent Prioritization will then discuss the list and see which of the top compounds could easily be paired together for the "repurposed" master protocol and which may require other avenues for testing, such as the "de novo" master protocol.
7. Step 7: For the agents that are chosen, the FNIH/Deloitte team will outreach to the companies, if they are not already part of ACTIV, to ensure appropriate drug supply. If there is enough agent to be tested or it can be manufactured in the next month, the agent will proceed for the "repurposed" master protocol. If not, the agent will be considered in for future testing based on the supply.

8. All agents not chosen for the first round that are not disqualified for safety will be re-evaluated for the next set of agents to be tested.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 10/29/2020 4:41:08 PM

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Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201029.pdf
Location: https://fnih.zoom. (b) (6)

Start: 10/29/2020 5:00:00 PM
End: 10/29/2020 6:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting in 20 minutes.

Thanks,
Stacey

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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Kim, Elizabeth [(b) (6) btolman [(b) (6) Wachtel,
Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael
[(b) (6) Rose Li [(b) (6) Dana Carluccio

[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [(b) (6) Mason, Stephen [Stephen. (b) (6) (b) (6) Connelly, Sarah [(b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [(b) (6) (b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]

Start: 3/17/2021 2:00:00 PM
End: 3/17/2021 3:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/16/2020 2:46:52 PM
To: Jens Lundgren [(b) (6)]
CC: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Jim Neaton [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6)] Srinivasan, Badhri [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; William Erhardt [(b) (6)] Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; (b) (6) Gelijns, Annetine [(b) (6)] Mark Polizzotto [(b) (6)] Ginny Kan [(b) (6)] Baker, Jason [(b) (6)] Roger Paredes [(b) (6)] Thompson, Taylor,M.D. [(b) (6)] Babiker, Ab [a. (b) (6)] Chen, Helen Q. [(b) (6)] Wachtel, Jonathan [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Kenny, Dermot [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pett, Sarah [(b) (6)] Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrettk2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccbr]; Eileen Denning [(b) (6)]
Subject: RE: ACTIV-3 Operations Team Meeting

Thanks, Jens!

Stacey J. Adam, PhD
Director, Cancer

Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Jens Lundgren < (b) (6)
Sent: Tuesday, June 16, 2020 10:44 AM
To: Adam, Stacey (FNIH) [T] < (b) (6)
Cc: Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Jim Neaton < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Eric Hughes < (b) (6) Srinivasan, Badhri < (b) (6) Goff, David (NIH/NHLBI) [E] < (b) (6) Nayak, Seema (NIH/NIAID) [E] < (b) (6) Victoria Davey < (b) (6) Kozak, Marina (OS/ASPR/BARDA) < (b) (6) McNay, Laura (NIH/NIAID) [E] < (b) (6) Tierney, John (NIH/NIAID) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) Patterson, Amy (NIH/NHLBI) [E] < (b) (6) Miller, Marissa A (NIH/NHLBI) [E] < (b) (6) Rachel Harrigan < (b) (6) William Erhardt < (b) (6) Reineck, Lora (NIH/NHLBI) [E] < (b) (6) (b) (6) Gelijns, Annetine < (b) (6) Mark Polizzotto < (b) (6) Ginny Kan < (b) (6) Baker, Jason < (b) (6) Roger Paredes < (b) (6) Thompson, Taylor,M.D. < (b) (6) Babiker, Ab < (b) (6) Chen, Helen Q. < (b) (6) Wachtel, Jonathan < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Desrosiers, Elizabeth A. < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Kenny, Dermot < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Pett, Sarah < (b) (6) Grace, Beth (NIH/NIAID) [C] < (b) (6) Barrett, Kevin (NIH/NIAID) [E] < (b) (6) Denning, Eileen < (b) (6) Eileen Denning < (b) (6)
Subject: Re: ACTIV-3 Operations Team Meeting

Dear all,

Is fully aware of this, and we should consider this to possible become part of standard-of-care once we have a more comprehensive report. In appendix I - and also discussed on call on Tuesday - we now outlined in the appendix a process for how SOC may/will evolve.

Can discuss more on call today of course - but there are some important operationel issues that Jim will present - and that can hopefully be resolved re path forward.

Thanks,

Jens

Prof. Jens Lundgren
Dept. Infectious Diseases, 8632
Rigshospitalet, University of Copenhagen
(b) (6) (PA); www.chip.dk

Den 16. jun. 2020 kl. 16.39 skrev Adam, Stacey (FNIH) [T] < (b) (6)

Hi All,

Here is the link from the actual RECOVERY website:
https://www.recoverytrial.net/files/recovery_dexamethasone_statement_160620_final.pdf
Just in case it is helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6)
Sent: Tuesday, June 16, 2020 10:22 AM
To: Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Jim Neaton < (b) (6) Jens Lundgren < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Eric Hughes < (b) (6) Srinivasan, Badhri < (b) (6) Goff, David (NIH/NHLBI) [E] < (b) (6) Nayak, Seema (NIH/NIAID) [E] < (b) (6) Victoria Davey < (b) (6) Kozak, Marina (OS/ASPR/BARDA) < (b) (6) McNay, Laura (NIH/NIAID) [E] < (b) (6) Tierney, John (NIH/NIAID) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) Patterson, Amy (NIH/NHLBI) [E] < (b) (6) Miller, Marissa A (NIH/NHLBI) [E] < (b) (6) Rachel Harrigan < (b) (6) William Erhardt < (b) (6) Reineck, Lora (NIH/NHLBI) [E] < (b) (6) (b) (6) Gelijns, Annetine (b) (6) (b) (6) Mark Polizzotto < (b) (6) Ginny Kan < (b) (6) Baker, Jason < (b) (6) Roger Paredes < (b) (6) Thompson, Taylor,M.D. · (b) (6) Babiker, Ab < (b) (6)
Cc: Chen, Helen Q. < (b) (6) Wachtel, Jonathan < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Desrosiers, Elizabeth A. (b) (6) b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Kenny, Dermot < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Pett, Sarah < (b) (6) Grace, Beth (NIH/NIAID) [C] < (b) (6) .gov>; Barrett, Kevin (NIH/NIAID) [E] < (b) (6) Denning, Eileen < (b) (6) Eileen Denning < (b) (6)
Subject: Re: ACTIV-3 Operations Team Meeting

Given benefit only in late stage diseases (based only on executive summary), our inclusion criteria excluding end organ failure in stage 1, early endpoint in stage 1, perhaps a consideration for stage 2 only.

From: "Rosenberg, Yves (NIH/NHLBI) [E]" < (b) (6)
Date: Tuesday, June 16, 2020 at 10:13 AM
To: "Adam, Stacey (FNIH) [T]" < (b) (6) James Neaton < (b) (6) Jens Lundgren (b) (6) "Read, Sarah (NIH/NIAID) [E]" < (b) (6) Eric Hughes < (b) (6) " (b) (6) < (b) (6) "Srinivasan, Badhri" (b) (6) "Goff, David (NIH/NHLBI) [E]" < (b) (6) "Nayak, Seema (NIH/NIAID) [E]" < (b) (6) Victoria Davey (b) (6) "Kozak, Marina (OS/ASPR/BARDA)" < (b) (6) " (b) (6) < (b) (6) "Tierney, John (NIH/NIAID) [E]" (b) (6) "Aggarwal, Neil (NIH/NHLBI) [E]" (b) (6) (b) (6) "Patterson, Amy (NIH/NHLBI) [E]" < (b) (6) "Miller, Marissa A (NIH/NHLBI) [E]" < (b) (6) Rachel Harrigan < (b) (6) William Erhardt < (b) (6) "Reineck, Lora (NIH/NHLBI) [E]" < (b) (6) " (b) (6) < (b) (6) "Gelijns, Annetine" < (b) (6) Mark Polizzotto < (b) (6) Virginia Kan < (b) (6) "Baker, Jason" < (b) (6) Roger Paredes < (b) (6) Taylor Thompson < (b) (6) Ab Babiker < (b) (6)

Cc: "Chen, Helen Q." < (b) (6) "Wachtel, Jonathan" < (b) (6) Karen Tountas < (b) (6) "Desrosiers, Elizabeth A." (b) (6) (b) (6) "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) "Kenny, Dermot" < (b) (6) "Parker, Ashley (NIH/OD) [E]" < (b) (6) Sarah Pett < (b) (6) " (b) (6) < (b) (6) "Barrett, Kevin (NIH/NIAID) [E]" < (b) (6) "Denning, Eileen" < (b) (6) Eileen Denning < (b) (6)
Subject: RE: ACTIV-3 Operations Team Meeting

Should we add this to the discussion? Should SOC arm and sample size be modified?
https://www.recoverytrial.net/news/low-cost-dexamethasone-reduces-death-by-up-to-one-third-in-hospitalised-patients-with-severe-respiratory-complications-of-covid-19

-----Original Appointment-----
From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Monday, June 15, 2020 9:28 PM
To: Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Reineck, Lora (NIH/NHLBI) [E]; (b) (6) Gelijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor,M.D.; Babiker, Ab
Cc: Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen; Eileen Denning
Subject: ACTIV-3 Operations Team Meeting
When: Tuesday, June 16, 2020 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.u (b) (6) .

Dear ACTIV-3 Operations Team,

Please find attached the agenda for tomorrow's meeting. If you have any additions or amendments, please let me know.

Jens or others, if you have slides that you would like me to pre-distribute, send them to me and I will get them out.

Thanks,
Stacey

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/5/2020 1:29:02 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: RE: A couple of additional notes from today's conversation

Hi David,

Yes, it sounds like we should hear more from Jacqueline Kirchner, as well as Skip Virgin, and also Mene Pangalos. I'm glad to join calls with all of these, but I'm wondering if Cliff can suggest someone at NIAID who knows a lot about mAbs and could help collect and distill this information for us.

With regard to the choice of CROs for the mAb trials, I'll need Cliff's insight on that too. Maybe we can discuss at the War Room tomorrow.

Francis

From: Wholley, David (FNIH) [T] < (b) (6)
Sent: Thursday, June 4, 2020 5:50 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6)
Subject: A couple of additional notes from today's conversation

Francis:
Sure hope your task force/OWS meeting with Moncef et. al. went well—anxious to hear results. A few additional fyis/requests to consider:

1) Jacqueline Kirchner of Gates Foundation (ex-Amgen, knows her stuff) approached Stacey and her co-chairs to say that Gates would be interested in combinatoric testing of mAbs. They have 2 in vitro tests (pseudo and live virus) as well as a Syrian Golden hamster model they are developing and are in discussion with several companies. Of course that will mean they want "in" on our testing platform, strategies, and results, but seems worth a conversation. Shall we arrange it, and whom with?
2) I think I ran to ground the source of the request that was brought up from Hilary Marston to have someone from ACTIV brief Janet, and it involves an issue you and Cliff may want to think about helping out on. We think the request came from Janet via Kevin Bugin, and involves Janet's repeated (and apparently frustrated) requests to get clarity from NIAID on the choice of CRO to run the mAB trials (or perhaps just the inpatient trial?). To their credit, DAIDS and DCR are doing their utmost to run the outpatient and inpatient mAb trials on a single unified

infrastructure: single DSMB, common clinical data capture and management platform, and a common CRO. The problem is that the CRO that they have chosen is PPD, and PPD is apparently the CRO chosen for all the NIAID vaccine trials as well. Janet and her team are worried that the choice of PPD for the mAbs will look biased, and that PPD may not really have the capacity to do everything. They would prefer to rapidly RFP this, include some of the BARDA CROs on the RFP, and move forward from there. We have been trying to use the ACTIV WG structure to arrange a call on this, but the DAIDS folks have balked, saying "we've got this, we'll talk about it later" (in other words "please go away"). Our guess is Janet is frustrated by this and is trying to find another route through Hilary. Taking full account of your statement on today's call that we need to support (and communicate well with) Janet, is this something you can help her with?

Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Young, John [(b) (6)
Sent: 5/30/2020 12:21:03 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) Annaliesa. (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hughes, Eric [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio

[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6)]

Subject: Re: ACTIV Preclinical working group (Tuesday meeting)

Thanks Joe. Minutes are clear and comprehensive. No further comments from my side.
Best regards
John

On Fri, May 29, 2020 at 9:41 PM Menetski, Joseph (FNIH) [T] (b) (6) wrote:

This time with the attachment.

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, April 14, 2020 6:43 PM
To: (b) (6) (b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) ; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin
Subject: ACTIV Preclinical working group (Tuesday meeting)
When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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US (Houston)

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Password: (b) (6)

Find your local number: https://fnih.zoom.us (b) (6)

--

John A.T. Young, PhD
VP and Global Head Infectious Diseases
Immunology, Infectious Diseases and Ophthalmology (I2O) Discovery and Translational Area
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/30/2020 2:02:32 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Thanks. Since Cliff demurred somewhat, I will wait for him to give me the high sign to send.

From: Collins, Francis (NIH/OD) [E] < (b) (6)
Sent: Wednesday, July 29, 2020 9:59 PM
To: Wholley, David (FNIH) [T] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Your reply is fine, and it's fine for you to send it.

Tx, FC

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Wednesday, July 29, 2020 5:59 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b Tabak, Lawrence (NIH/OD) [E] (b) (6) Anderson, James (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Francis, I composed the following reply to Robert for your consideration. I'm happy to send it (he wrote to both of us) or you can; feel free to edit of course in either case. Cliff, please weigh in on how I have characterized the NIAID study you mentioned this morning. Thanks

Hi Robert:

(b) (5)

Regards,
David

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Wednesday, July 29, 2020 7:43 AM
To: Freire, Maria (FNIH) [T] < (b) (6) ; Wholley, David (FNIH) [T] (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) ; Tabak, Lawrence (NIH/OD) [E] < (b) (6) ; Anderson, James (NIH/OD) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: FW: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

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From: Plenge, Robert < (b) (6)
Sent: Wednesday, July 29, 2020 7:33 AM
To: Wholley, David (FNIH) [T] (b) (6) Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data (here, here, here, here), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

From: "Melencio, Cheryl (FNIH) [T]" < (b) (6) on behalf of "Wholley, David (FNIH) [T]" < (b) (6)
Date: Tuesday, July 28, 2020 at 10:55 PM
To: "Austin, Christopher (NIH/NCATS) [E]" (b) (6) >, "Bancel, Stephane" < (b) (6) "Carter, Kara" (b) (6) (b) (6) "Cavaleri, Marco" < (b) (6) "Cihlar, Tomas" (b) (6) "Collins, Francis (NIH/OD) [E]" (b) (6) "Corey, Larry" < (b) (6) "Culp, Michelle (NIH/OD) [E]" (b) (6) b) (6) "Disbrow, Gary (OS/ASPR/BARDA)" < (b) (6) "Dolsten, Mikael" < (b) (6) "Erbelding, Emily (NIH/NIAID) [E]" < (b) (6) "Erck, Stan" < (b) (6) >, "Fauci, Anthony (NIH/NIAID) [E]" (b) "Freire, Maria (FNIH) [T]" < (b) (6) "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) "Gibbons, Gary (NIH/NHLBI) [E]" < (b) (6) "Hudson, Thomas" (b) (6) , "James, Stephanie (FNIH) [T]" < (b) (6) , "Johnson, Robert (OS/ASPR/BARDA)" (b) (6) "Kramer, Lynn" (b) (6) >, "Lane, Cliff (NIH/NIAID) [E]" (b) (6) "Lepore, John" (b) (6) (b) (6) "Marks, Peter (FDA/CBER)" < (b) (6) "Marston, Hilary (NIH/NIAID) [E]" ("Mascola, John (NIH/VRC) [E]" (b) (6) , "Meeker, David" (b) (6) "Menetski, Joseph (FNIH) [T]" < (b) (6) , "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" (b) (6) "Pandya, Hitesh" (b) (6) "Pangalos, Mene" < (b) (6) "Pao, William" < (b) (6) "Parker, Ashley (NIH/OD) [E]" < (b) (6) "Paul, Steve" (b) (6) , "Perlmutter, Roger" < (b) (6) "Plenge, Robert" (b) (6) "Plump, Andy" (b) (6) Rachel Ramoni < (b) (6) "Rasi, Guido" < (b) (6) "Reed, John" < (b) (6) "Reese, David" (b) (6) , "Rouse, Doris" < (b) (6) "Santos, Michael (FNIH) [T]" < (b) (6) "Skovronsky, Daniel" < (b) (6) >, "Stein, Peter (FDA/CDER)" < (b) (6) "Stoffels, Paul" (b) (6) >, "Tabak, Lawrence (NIH/OD) [E]" (b) (6) (6) "Talley, Michael"(>, "Tsai, John"

< (b) (6) , "Vessey, Rupert" < (b) (6) , "Virgin, Skip" (b) (6) , "Wholley, David (FNIH) [T]"((b) (6) , "Woodcock, Janet (FDA/CDER)" (b) (6) (6) , "Young, John" (b) (6) , "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) , "Desrosiers, Betsy" (b) (6) >, Eric Hughes (b) (6) , "Jansen, Kathrin" (b) (6) (b) (6) , "Kurilla, Michael (NIH/NCATS) [E]" (b) (6) >, "Lowy, Douglas (NCI)" (b) (6) "Read, Sarah (NIH/NIAID) [E]" < (b) ((b) (6) , "Young, John" < (b) (6)

Cc: "Bianchi, Diana (NIH/NICHD) [E]" < (b) (6) , "Byrnes, Noni (NIH/CSR) [E]" (b) (6) , "Glass, Roger (NIH/FIC) [E]" (b) (6) , "Hodes, Richard (NIH/NIA) [E]" (b) (6) , "Koob, George (NIH/NIAAA) [E]" (b) (6) , "Koroshetz, Walter (NIH/NINDS) [E]" < (b) (6) "Langevin, Helene (NIH/NCCIH) [E]" (b) (6)) (6) , "Norris, Andrea (NIH/CIT) [E]" < (b) (6) , "Perez-Stable, Eliseo (NIH/NIMHD) [E]" (b) (6) , "Rodgers, Griffin (NIH/NIDDK) [E]" < (b) (6) , "Schwetz, Tara (NIH/OD) [E]" (b) (6) , "Sharpless, Norman (NIH/NCI) [E]" < (b) (6) "Tucci, Debara (NIH/NIDCD) [E]" < (b) (6) , "Tumminia, Santa (NIH/NEI) [E]" (b) (6) , "Volkow, Nora (NIH/NIDA) [E]" < (b) (6) "Woychik, Rick (NIH/NIEHS) [E]" (b) (6) , "Adam, Stacey (FNIH) [T]" < (b) (6) , "Alvarez, Rosa" (b) (6) >, "Anderson, Margaret" (b) (6) , "Chen, Helen" (b) (6) >, "Elsaid, Olivia" < (b) (6) , "Gonzalez, Nina" < (b) (6) , "James, Stephanie (FNIH) [T]" < (b) (6) , "Menetski, Joseph (FNIH) [T]" < (b) (6) rg>, "Santos, Michael (FNIH) [T]" (b) (6) , "Stratton, Ben" (b) (6) >, "Tolman, Brett" < (b) (6) >, "Tountas, Karen (FNIH) [T]" < (b) (6) , "Wachtel, Jonathan" < (b) (6) , "Wholley, David (FNIH) [T]" (b) (6) >, "Anderson, James (NIH/OD) [E]" (b) (6) , "Burklow, John (NIH/OD) [E]" < (b) (6) "Castillejos, Carlos" (b) (6) "Culp, Michelle (NIH/OD) [E]" < (b) (6) FNIH Central Account (b) (6) , "Freire, Maria (FNIH) [T]" < (b) (6) , "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) , "Wolinetz, Carrie (NIH/OD) [E]" (b) (6) >, "Burklow, John (NIH/OD) [E]" < (b) (6) , "Gorman, Greta (FNIH) [T]" (b) (6) , "Hallett, Adrienne (NIH/OD) [E]" (b) (6) , "Meltzer, Abbey (FNIH) [T]" (b) (6) , "Myles, Renate (NIH/OD) [E]" (b) (6) , "Melencio, Cheryl (FNIH) [T]" < (b) (6)

Subject: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Resent-From: (b) (6)

[Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

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Find your local number: https://fnih. (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 11:37:18 PM
To: Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6) Keith Gottesdiener [(b) (6) Elliott Levy [(b) (6) Wung, Peter /US [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6) Salathin, Carla [(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [(b) (6)
Subject: Initial Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #12
Attachments: ACTIV_Therapeutics-Clinical_Agent Prioritization Subgroup_21May2020_Key Takeaways.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the initial follow-up to today's meeting. High level summary and action items are included, as well as a list of the members of the sub-teams for review. Please take a look and let me know if you would like to move sub-teams or be assigned to one.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile:(
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From: Alvarez, Rosa Maria [(b) (6)
Sent: 8/19/2020 1:18:30 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6)) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

Subject: RE: ACTIV Preclinical full working group

Attachments: 2020-08-12_Preclinical_WG_Summary_vF.docx

Hi all,

Please see attached for our notes from last week's meeting. Also below is our agenda for today's meeting.

Look forward to our discussion today.

Agenda Topic	Duration	Facilitator
Discuss BEI viral stock production updates	15 mins	Clint Florence
Discuss 'match-making' process for NHP studies and small animals/ in vitro studies	15 mins	Joe Menetski
Discuss Sub Group updates ○ In vivo Strategy ○ Data Portal Implementation ○ Preclinical Network Implementation	25 mins	Nancy Haigwood Clint Florence Sam Jonson Liz Ottinger John Young
Align on action items and next steps	5 mins	Joe Menetski Rosa Alvarez

Best Regards,
Rosa

Rosa M. Álvarez
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-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] < (b) (6)
Sent: Tuesday, April 14, 2020 6:44 PM
To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]
Subject: ACTIV Preclinical full working group
When: Wednesday, August 19, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/ (b) (6)

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

Sent: 1/12/2021 9:53:33 PM

To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Reed, John (b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael (b) (6) Tsai, John (b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John

(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse (b) (6) Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6)

CC: Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter];

Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Krack, Kimberly [kimberly]; (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Lever, Susan (b) (6)]; Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Martin, Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [(b) (6)]; Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riggin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6)

Subject: ACTIV Leadership Team Call #14
Location: https://fnih.zoom.us/ (b) (6)

Start: 3/18/2021 2:30:00 PM
End: 3/18/2021 4:00:00 PM
Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Meltzer, Abbey (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim;

Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Magbie-Robinson, Kim; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/15/2020 10:09:39 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: ACTIV TX-Clinical WG Master Protocol Subgroup - 2nd Meeting
Location: https://zoom.us/j/ (b) (6)

Start: 4/16/2020 3:00:00 PM
End: 4/16/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER)
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you for your interest and participation in the Master Protocol sub-group. Per our conversation today, we are scheduling another call for this group tomorrow at 11am as we have a good quorum. We do understand that some will not be able to make it. We will be sure to distribute a summary after for all.

Please note that this is not a fixed timeslot for upcoming sub-group meetings. After this first sub-group meeting, we will send out a scheduling link to coordinate the best time for sub group meetings moving forward.

Kind regards,
Stacey, on behalf of the ACTIV TX-Clinical WG

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/25/2020 1:46:33 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [(b) (6)
Subject: Follow-up from the ACTIV TX-Clinical Master Protocol Subgroup Meeting #7
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_24Apr2020 Meeting Guide.pdf; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 7_Key Takeaways_04232020.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the high level summary and action items from today's call. Please let me know if you have any additions or amendments.

Also, for those joining us, please find attached the slides for tomorrow's discussion on sample size and recovery ratios/power calculations.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

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To: (b) (6) (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)

CC: Diamond, Michael [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D (b) (6) ; Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Attachments: 2020-09-16_Preclinical_WG_Summary_F1.docx

Dear Team,

Here are the minutes from this weeks' meeting. Please let me know if you have any questions or concerns.

Thank you,

Best regards,
Joe

Joseph P. Menetski Ph.D.
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FNIH PANDEMIC RESPONSE FUND

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

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CC: Diamond, Michael [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: RE: ACTIV Preclinical full working group
Attachments: 2020-06-10_Preclinical_WG_Summary_F2.docx

Dear Preclinical working group members and attendees,

Please find the minutes from last weeks meeting attached. Feel free to contact me if you have any questions.

Best regards,
Joe

-----Original Appointment-----
Subject: ACTIV Preclinical full working group
When: Wednesday, June 10, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/ (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]

Sent: 6/10/2020 5:33:26 PM

To: Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers , Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Takas, Therese [(b) (6) Vincent, Mike [(b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]

CC: Wachtel, Jonathan [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kenny, Dermot [(b) (6) Kublin, James [(b) (6) Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
(b) (6)

Subject: Summary and action items - CT Capacity WG meeting #15
Attachments: Clinical_Trial_Capacity_Working_Group_Meeting_15_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #15 (June 9, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, June 16 at 9 am eastern US time.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

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Sent: 6/4/2020 9:49:48 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: A couple of additional notes from today's conversation

Francis:
Sure hope your task force/OWS meeting with Moncef et. al. went well—anxious to hear results. A few additional fyis/requests to consider:

1) Jacqueline Kirchner of Gates Foundation (ex-Amgen, knows her stuff) approached Stacey and her co-chairs to say that Gates would be interested in combinatoric testing of mAbs. They have 2 in vitro tests (pseudo and live virus) as well as a Syrian Golden hamster model they are developing and are in discussion with several companies. Of course that will mean they want "in" on our testing platform, strategies, and results, but seems worth a conversation. Shall we arrange it, and whom with?
2) I think I ran to ground the source of the request that was brought up from Hilary Marston to have someone from ACTIV brief Janet, and it involves an issue you and Cliff may want to think about helping out on. We think the request came from Janet via Kevin Bugin, and involves Janet's repeated (and apparently frustrated) requests to get clarity from NIAID on the choice of CRO to run the mAB trials (or perhaps just the inpatient trial?). To their credit, DAIDS and DCR are doing their utmost to run the outpatient and inpatient mAb trials on a single unified infrastructure: single DSMB, common clinical data capture and management platform, and a common CRO. The problem is that the CRO that they have chosen is PPD, and PPD is apparently the CRO chosen for all the NIAID vaccine trials as well. Janet and her team are worried that the choice of PPD for the mAbs will look biased, and that PPD may not really have the capacity to do everything. They would prefer to rapidly RFP this, include some of the BARDA CROs on the RFP, and move forward from there. We have been trying to use the ACTIV WG structure to arrange a call on this, but the DAIDS folks have balked, saying "we've got this, we'll talk about it later" (in other words "please go away"). Our guess is Janet is frustrated by this and is trying to find another route through Hilary. Taking full account of your statement on today's call that we need to support (and communicate well with) Janet, is this something you can help her with?

Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

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To: (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: ACTIV Preclinical working group (Tuesday meeting)
Location: https://fnih.zoom. (b) (6)

Start: 4/22/2020 2:00:00 PM
End: 4/22/2020 3:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Changing time for preclinical WG

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6) d (b) (6) MHUGHES@SDAC.HARVARD.EDU; (b) (6) (b) (6) (b) (6) (b) (6) Eron, Joe (b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; LH (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6) Eron, Joseph J Jr (b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Chen, Helen Q. [(b) (6)

Subject: Canceled: HOLD for Potential ACTIV-2 Writing Team Meeting
Location: https://fnih.zoom.us (b) (6)

Start: 6/11/2020 2:00:00 PM
End: 6/11/2020 3:00:00 PM
Show Time As: Free

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Hi ACTIV-2 Writing Team,

Cancelling as we do not yet have comments from FDA.

Thanks,

Stacey

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/14/2020 12:59:44 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: FW: Materials for August 14 ACTIV Executive Committee Teleconference

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From: Melencio, Cheryl (FNIH) [T] < (b) (6)
Sent: Friday, August 14, 2020 8:57 AM
To: Wholley, David (FNIH) [T] < (b) (6)
Subject: FW: Materials for August 14 ACTIV Executive Committee Teleconference

FYI

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

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From: Barasch, Kimberly (NIH/NIAID) [C] < (b) (6)
Sent: Friday, August 14, 2020 8:15 AM
To: Melencio, Cheryl (FNIH) [T] (b) (6)
Subject: RE: Materials for August 14 ACTIV Executive Committee Teleconference

Hi Cheryl,
Dr. Fauci decided this morning that he is going to try and call in from the car on the way back to NIH from the White House. There is a good chance he will be ~15 minutes late join.

Thank you,
Kim

Kim Barasch [C]

Office of the Director
National Institute of Allergy & Infectious Diseases
301.496.2263
(b) (6)

From: Melencio, Cheryl (FNIH) [T] (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Thursday, August 13, 2020 10:20 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) Dolsten, Mikael (b) (6) Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E] (b) (6) ; Marks, Peter (FDA/CBER) (b) (6) ; Pao, William (b) (6) Plump, Andrew < (b) (6) Stoffels, Paul (b) (6) Woodcock, Janet (FDA/CDER) < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy (b) (6) >; Eric Hughes (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) >; Lowy, Douglas (NCI) < (b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6) ; Young, John < (b) (6) Wholley, David (FNIH) [T] < (b) (6)
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Austin, Christopher (NIH/NCATS) [E] < (b) (6) Burklow, John (NIH/OD) [E] (b) (6)) (6) Castillejos, Carlos < (b) (6) Culp, Michelle (NIH/OD) [E] (b) (6) FNIH Central Account (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) Gadbois, Ellen (NIH/OD) [E] (b) (6) Hallett, Adrienne (NIH/OD) [E] < (b) (6) Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] (b Wolinetz, Carrie (NIH/OD) [E] <g (Melencio, Cheryl (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] (b) (6) >; Alvarez, Rosa (b) (6) Anderson, Margaret (b) (6) >; Chen, Helen (b) (6) Elsaid, Olivia (b) (6) Gonzalez, Nina (b) (6) >; Hawk, Harrison <(Menetski, Joseph (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] (b) (6) >; Stratton, Benjamin < (b) (6) Tolman, Brett < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan (b) (6)
Subject: Materials for August 14 ACTIV Executive Committee Teleconference
Importance: High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **12:00 – 1:00 PM Eastern U.S. time** tomorrow, Friday, August 14. I have also attached notes from our July 29 Leadership Team meeting as well as our last EC meeting on July 15. As you know we will be hearing from two Working Groups instead of four, **so the co-chairs have decided to make this call as well as future EC and LT calls going forward 60 minutes in length instead of 90 minutes.**

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Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 7/15/2020 5:38:24 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Kathrin.Ja (b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Arvin, Ann [(b) (6) Beth Bell ((b) (6) [(b) (6) (b) (6) Cavaleri Marco [(b) (6) (b) (6) (b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [(b) (6) (b) (6) (b) (6) Marks, Peter (FDA/CBER) [(b) (6) Mascola, John (NIH/VRC) [E] (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Nelson Michael [(b) (6) Offit, Paul [(b) (6) Seals, Jonathan (OS/ASPR/BARDA) [(b) (6)]; (b) (6) (b) (6) Tal Zaks [Tal. (b) (6)]; (b) (6) (b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [(b) (6) Johnson, Maureen (NIH/NCI) [E] (b) (6) (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [(b) (6) (b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6)]; Wholley, David (FNIH) [T] [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA) [(b) (6)]; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [kneuzil@som.umaryland.edu]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [(b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [(b) (6) Gonzalez, Nina [(b) (6) 'Wachtel, Jonathan' [(b) (6) Stratton, Benjamin [(b) (6) Anderson, Margaret [(b) (6) (b) (6) (b) (6) Bethany Stokes [(b) (6) Kathleen Callahan [(b) (6) Arvin, Ann [(b) (6) Young, John (b) (6)

Subject: ACTIV Vaccines Working Group meeting
Location: Webex: https://nih.webex.com/n (b) (6)

Start: 7/29/2020 2:00:00 PM
End: 7/29/2020 3:00:00 PM
Show Time As: Busy

-----Original Appointment-----
From: Santos, Michael (FNIH) [T] < (b) (6)
Sent: Tuesday, June 30, 2020 3:18 PM

To: Santos, Michael (FNIH) [T]; Kathrin. (b) (6) Lowy, Douglas (NIH/NCI) [E]; Arvin, Ann; Beth Bell ((b) (6) (b) (6) Cavaleri Marco; (b) (6) (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes, Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; Seals, Jonathan (OS/ASPR/BARDA); Jim.Tart (b) (6) (b) (6) Tal Zaks; (b) (6) (b) (6)
Cc: Tolman, Brett; Jessica. (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; 'Wachtel, Jonathan'; Stratton, Benjamin; Anderson, Margaret; (b) (6) ; (b) (6) Bethany Stokes; Kathleen Callahan; Arvin, Ann; Young, John
Subject: ACTIV Vaccines Working Group meeting
When: Wednesday, July 29, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

Sent: 9/4/2020 12:46:24 PM

To: (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)

CC: (b) (6) Reynolds, Lindsey [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio (b) (6) ; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen (b) (6)

Subject: ACTIV Preclinical full working group

Attachments: 2020-09-02_Preclinical_WG_Summary_F1.docx

Dear Team,

Here are the minutes from our last meeting. Thank you for your participation.

I hope you all have a great Labor Day Weekend.

Joe

Joseph P. Menetski Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6) | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 12/10/2020 4:47:14 PM

To: Jacqueline Kirchner [(b) (6) Garner, Carl (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark (b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [Sandeep.M. (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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CC: Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes [(b) (6) Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Lumsden, Joanne (NIH/NCATS) [C]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting
Attachments: ACTIV_TX-Clinical WG Meeting_20201210.pdf
Location: https://fnih.zoom. (b) (6)

Start: 12/10/2020 6:00:00 PM
End: 12/10/2020 7:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Jacqueline Kirchner; Garner, Carl; Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Coady, Sean (NIH/NHLBI) [E]; Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Anderson, Margaret; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting. Looking forward to see you all there.

Thanks,
Stacey

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From: Connelly, Sarah [(b) (6)
Sent: 1/5/2021 9:56:22 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li

(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) (b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [(b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group Members,

Please see below for the agenda for tomorrow's meeting at 10:00 AM ET. If you have any questions or items to add, please let us know.

Agenda Topic	Duration	Facilitator
Emerging Viral Sequence Subgroup - Updates	20 mins	John Young Christine Colvis Joe Menetski
Pandemic Preparedness Preclinical Agent Development - Updates	20 mins	Christine Colvis Joe Menetski
Discuss Subgroup updates ○ Preclinical prioritization ○ In vivo strategy ○ Field Guides ○ Viral Stocks ○ Data portal implementation ○ Emerging Sequences	15 mins	John Young Nancy Haigwood Clint Florence Sam Jonson Joe Menetski
Align on action items and next steps	5 mins	Joe Menetski Sarah Connelly

Looking forward to talking to everyone tomorrow!

All the best,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
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-----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] < (b) (6)
Sent: Friday, October 2, 2020 2:19 PM
To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) (b) (6)
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah; (b) (6) Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; (b) (6)
Subject: ACTIV Preclinical full working group
When: Wednesday, January 6, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us (b) (6)

Changing time for preclinical WG

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Sent: 5/4/2020 9:19:15 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterton, Joan [(b) (6) Collins, Sylva (FDA/CDER) [Sylva. (b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6) Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6) Farley, John (FDA/CDER) [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]; Patterson, Amy (NIH/NHLBI) [E] [(b) (6) Judy Currier [(b) (6) Pamela Tenaerts, M.D. [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [(b) (6)

Subject: ACTIV TX-Clinical Master Protocol Ad Hoc Meeting
Location: https://fnih.zoom.us/ (b) (6)

Start: 5/5/2020 6:00:00 PM
End: 5/5/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]; Patterson, Amy (NIH/NHLBI) [E]
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Hoots, W. Keith (NIH/NHLBI) [E]

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Sent: 10/8/2020 6:35:51 PM

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Subject: Slides from ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201008.pdf

Dear ACTIV TX-Clinical WG,

Apologies for not getting these out ahead of the meeting, but please find attached the slides from today's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/12/2020 5:10:25 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [tomas.cihlar@gilead.com]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Vessey, Rupert [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; (b) (6) Villafana, Tonya [(b) (6) Bancel, Stephane [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John (b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Plump, Andy [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Tsai, John (b) (6)

CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6)]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [(b) (6) Chen, Helen Q. [(b) (6) Connelly, Sarah [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6)]; Mendelson, Jesse (b) (6) asorosa [(b) (6) Stratton, Benjamin [(b) (6) btolman [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth

(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [ann.protasiewicz@pfizer.com]; Riccobene, Kim [(b) (6) .com]; Riggin, Mary (b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [donna. (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Tajalli, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [(b) (6) Zottoli, Jessica (b) (6)) Vessey, Rupert [(b) (6) Regan, Donna M [donna. (b) (6) Grant, Sarah (b) (6) (b) (6) Plenge, Robert [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nasr, Hana [(b) (6) Hoban, Michelle [(b) (6)

Subject: ACTIV Leadership Team Meeting #11
Attachments: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION
Location: https://fnih.zoom.us/ (b) (6)

Start: 12/16/2020 3:00:00 PM
End: 12/16/2020 4:30:00 PM
Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Victoria Davey; (b) (6) Villafana, Tonya

Optional Attendees: Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada

(NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Vessey, Rupert; Regan, Donna M; Grant, Sarah; Plenge, Robert; Lowy, Douglas (NIH/NCI) [E]; Nasr, Hana

Extending the call by 30 minutes per discussion at Nov. 19 Leadership Team call

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 7/11/2020 3:09:34 AM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish (b) (6)) (6)]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV

DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6)

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [jwachtel@deloitte.com]; Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6)

Subject: Follow-up to ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: 2020-07-09_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical Working Group,

Please find attached the summary for yesterday's meeting! Thank you to you all for your participation.

Happy Friday,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) ; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (6) (b) (6) ; (b) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [(b) (6) Mason, Stephen [(b) (6) (b) (6) Diamond, Michael [(b) (6)

Start: 9/16/2020 2:00:00 PM
End: 9/16/2020 3:00:00 PM

Recurrence: (none)

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/6/2020 4:53:25 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

OK. Did we get any read-ahead material from Jacqueline?

From: Menetski, Joseph (FNIH) [T] < (b) (6)
Sent: Saturday, June 6, 2020 12:53 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Wood, Gretchen (NIH/OD) [E] < (b) (6)
Cc: Adam, Stacey (FNIH) [T] < (b) (6)
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

The meeting has these invites.

Wholley, David (FNIH) [T]
Adam, Stacey (FNIH) [T]
Menetski, Joseph (FNIH) [T]
Jacqueline Kirchner
Woodcock, Janet (FDA/CDER)
Collins, Francis (NIH/OD) [E]

joe

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Saturday, June 6, 2020 12:50 PM
To: Wholley, David (FNIH) [T] (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) Wood, Gretchen (NIH/OD) [E] (b) (6)
Cc: Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] (b) (6)
Subject: RE: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Sincere apologies, I just saw this message. I don't know who has been invited to join this call, can someone fill me in?

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Saturday, June 6, 2020 7:21 AM
To: Menetski, Joseph (FNIH) [T] (b) (6) ; Collins, Francis (NIH/OD) [E] (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T] (b) (6) ; Wood, Gretchen (NIH/OD) [E] (b) (6) >
Cc: Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] (b) (6)
Subject: Re: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

I noticed a label on today's call "data shared in confidence". Does this give us pause in terms of inviting additional experts?
Get Outlook for iOS

From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Friday, June 5, 2020 6:43:53 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) >
Cc: Wholley, David (FNIH) [T] (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] < (b) (6)
Subject: Experts for ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear Francis,

Stacey and I have polled our working groups, asking for suggestions and volunteers that could provide expert opinion on monoclonal antibody testing during conversations with Skip Virgin and Jacqueline Kirchner. The groups are very enthusiastic about this topic and we received almost 30 names of experts in the field. Given the time frame that we are asking for people to join these calls, I have picked 4 people that are already involved in ACTIV to invite to the Jacqueline Kirchner call tomorrow and 6 to invite to the call with Skip on Monday.

As I said, there were many more, but I think we would want to talk to them first, before bringing them into a discussion like this.

I am happy to invite these folks tonight, if it would be easier and agreeable to you (I would cc you). Or I have drafted a short email for you to send them below (as always, feel free to modify).

Best regards,
Joe

Memo: ACTIV discussion on choosing neutralizing antibodies and mixtures

Dear xx,
The NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is setting up protocols to assess monoclonal neutralizing antibodies as therapies against COVID-19. During discussions with the ACTIV Leadership Team and in collaboration with the upcoming Monoclonal Antibody Round Table, we have a meeting to gather additional expert opinion on the appropriate preclinical testing approaches, particularly for choosing mixtures or cocktails of neutralizing Abs. I would like to have your input in the important topic during a meeting [tomorrow at 1pm ET; or Monday at 2:45pm ET]. I realize this is short notice, but the ACTIV program is moving very fast and our rapid response is essential. I hope you can join me in this important discussion.

Sincerely,
Francis Collins

Names and emails below.

Saturday call with J Kirchner:
Peter Adams, (OS/ASPR/BARDA); (b) (6)
Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec ; (b) (6)
John W Mellors at University of Pittsburgh; (b) (6)

Monday call with Skip Virgin:
Peter Adams, (OS/ASPR/BARDA); (b) (6)
Michael Diamond at Washington University at St Louis; (b) (6)
Kara Carter at EvoTec ; (
John W Mellors at University of Pittsburgh; (b) (6)
Randall Tressler, (NIH/NIAID); (b) (6)
Sebastian Breuer, Roche; (b) (6)

Joseph P. Menetski Ph.D.
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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] [(b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]

CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [(b) (6) Mason, Stephen [Stephen. (b) (6) (b) (6) Connelly, Sarah [(b) (6) (b) (6) Gonzalez, Nina [(b) (6) Reynolds, Lindsey [(b) (6)

Start: 11/5/2020 3:00:00 PM
End: 11/5/2020 4:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Required Attendees: (b) (6) Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Optional Attendees: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah; (b) (6) Reynolds, Lindsey

While not unanimous, more people were able to make the 5th at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/21/2020 1:29:07 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; (b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6)]; (b) (6) Arvin, Ann [(b) (6) Beth Bell ((b) (6) [(b) (6) (b) (6) Cavaleri Marco [(b) (6) (b) (6) (b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [(b) (6) (b) (6) (b) (6) Marks, Peter (FDA/CBER) [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) (b) (6) Offit, Paul [(b) (6) Seals, Jonathan (OS/ASPR/BARDA) [(b) (6) (b) (6) Tal Zaks [(b) (6) (b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [(b) (6) Johnson, Maureen (NIH/NCI) [E] [(b) (6) (b) (6) Jeneffer Haynes [(b) (6)]; (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [(b) (6) (b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [felicia.qashu@nih.gov]; Culp, Michelle (NIH/OD) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Desrosiers, Betsy [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John [(b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA) [(b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [(b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [(b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [(b) (6) Gonzalez, Nina [(b) (6) Wachtel, Jonathan [(b) (6) Stratton, Benjamin [(b) (6) Anderson, Margaret [(b) (6) (b) (6) (b) (6) Bethany Stokes [(b) (6) Arvin, Ann [(b) (6) Biggerstaff, Matthew (CDC/DDID/NCIRD/ID) [(b) (6) Cohen, Myron [(b) (6) (b) (6) .com; Erbelding, Emily (NIH/NIAID) [E] [(b) (6) (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [(b) (6) (b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID) [E] [(b) (6) (b) (6) Marovich, Mary (NIH/NIAID) [E] [(b) (6)]; (b) (6) (b) (6) Laurent Humeau [(b) (6) (b) (6) Cheryl Keech [(b) (6) Hughes, Eric [(b) (6) Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]

Subject: ACTIV Vaccines Working Group meeting
Location: Webex: https://nih.webex.com/r (b) (6)

Start: 5/28/2020 6:00:00 PM
End: 5/28/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell ((b) (6) (b) (6) Cavaleri Marco; (b) (6) (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,

Optional Attendees: Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA); Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6) Tal Zaks Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Ann Arvin; Biggerstaff, Matthew (CDC/DDID/NCIRD/ID); Cohen, Myron; Denny, Joshua (NIH/OD) [E]; ' (b) (6) Erbelding, Emily (NIH/NIAID) [E]; ' (b) (6) ' (b) (6) Gruber, Marion (FDA/CBER); ' (b) (6) ' (b) (6) Ledgerwood, Julie (NIH/NIAID) [E]; ' (b) (6) Marovich, Mary (NIH/NIAID) [E]; ' (b) (6) ' (b) (6) 'Laurent Humeau'; ' (b) (6) Cheryl Keech

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]

Sent: 7/1/2020 3:54:31 PM

To: Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers , Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Takas, Therese [(b) (6) Vincent, Mike [(b) (6) Wachtel, Jonathan (b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kenny, Dermot [(b) (6) Kublin, James [(b) (6) Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Ardiff, Bernadette

[(b) (6) Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth (b) (6) Mueller-Reichenstein, Petra (b) (6) ; Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]

Subject: Summary and action items - CT Capacity WG meeting #17

Attachments: Clinical_Trial_Capacity_Working_Group_Meeting_17_Summary_final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #17 (June 30, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, July 14 at 9 am eastern US time. In the mean time, the playbook development teams will be assembling materials the topics: eCOA/BYOD/Hybrid; eConsent; Site Training/Tools; Remote Monitoring; and Home Nursing (nearly complete). Many thanks to all involved in these efforts!

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

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From: Chen, Helen Q. [(b) (6)
Sent: 9/9/2020 8:10:48 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]
Subject: FW: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Ashley,

Please see below a question from Neil. My understanding is it will be a feature once it's live on the website - is that correct? Please feel free to provide any additional information / clarification that would help address Neil's inquiry. Thank you!

Warm regards,
Helen

-----Original Message-----
From: Aggarwal, Neil (NIH/NHLBI) [E] (b) (6)
Sent: Wednesday, September 9, 2020 4:07 PM
To: Chen, Helen Q. < (b) (6)
Subject: [EXT] RE: ACTIV Therapeutics-Clinical Working Group Meeting

Thanks Helen. This has the potentially to be a really useful document. At this point, should we be able to see agent information if we hover over the black circle with an A in it? If so, that feature does not seem to be working (at least not for me).

Best,
Neil

Neil Aggarwal, MD
Chief, Lung Biology and Disease Branch
Division of Lung Diseases / NHLBI / NIH

-----Original Message-----
From: Chen, Helen Q. < (b) (6)
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) Bozzette, Sam (NIH/NCATS) [E] < (b) (6)
Butterton, Joan < (b) (6) De Claro, R. Angelo (FDA/CDER) < (b) (6)
Draghia-Akli, Ruxandra < (b) (6) Eisner, Mark < (b) (6) Gottesdiener, Keith
< (b) (6) Eric Hughes (b) (6) Judy Currier
< (b) (6) Kim, Elizabeth < (b) (6) LaVange, Lisa < (b) (6)
Levy, Elliot < (b) (6) Mellors, John W < (b) (6) Menon, Sandeep
< (b) (6) Parker, Ashley (NIH/OD) [E] <ashley. (b) (6) Patel, Naimish
< (b) (6) Peppercorn, Amanda < (b) (6) Poole, Mike
< (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
(NIH/NIAID) [E] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen, Yuan Li
(FDA/CDER) <Yuan.Li. (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Wholley, David
(FNIH) [T] < (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) Collins, Sylva
(FDA/CDER) < (b) (6) Amanda Peppercorn < (b) (6) Garner, Carl
< (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Koroshetz, Walter
(NIH/NINDS) [E] < (b) (6) Timothy Burgess < (b) (6) Reineck, Lora
(NIH/NHLBI) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6)
Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]
< (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]
< (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Jacqueline Kirchner
< (b) (6) Beigel, John (NIH) [E] < (b) (6) Phillips, L
Revell CIV DTRA RD (USA) (b) (6) >; Petrovick, Martha - 0449 - MITLL
< (b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E]
< (b) (6)
Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy
(b) (6) >; Jansen, Kathrin < (b) (6) Kurilla, Michael
(NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Young, John
< (b) (6) Biggs, Mary < (b) (6) Butcher, Tina (b) (6)
Demarcus < (b) (6) Macone, Erin < (b) (6) Melencio, Cheryl (FNIH) [T]

< (b) (6) Salathin, Carla < (b) (6) Tountas, Karen (FNIH) [T]
< (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) James, Stephanie (FNIH) [T]
(b) (6) >; Wachtel, Jonathan (b) (6) >; btolman (b) (6) om>; Alvarez,
Rosa Maria (b) (6) >; Gonzalez, Nina < (b) (6) Dana Carluccio
< (b) (6) Rose Li Central Account (b) (6) >; Margaret
Anderson < (b) (6) Lucas Smalldon < (b) (6) Stratton,
Benjamin < (b) (6) (b) (6) Mollica, Linda /US
< (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Patterson, Amy
(NIH/NHLBI) [E] < (b) (6) Rubin, Daniel B. (FDA/CDER) <daniel. (b) (6) Marston,
Hilary (NIH/NIAID) [E] (b) (6) >; Wung, Peter /US < (b) (6) ; Hoots, W. Keith
(NIH/NHLBI) [E] (b) (6) >; Groesch, Mary (NIH/NHLBI) [E] < (b) (6) Shipp,
Allan (NIH/NHLBI) [E] (b) (6) >; Kindzelski, Andrei (NIH/NHLBI) [E]
(b) (6) >; Hone, David M (Dave) CIV DTRA J9 (USA) (b) (6)
Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) <ronald.b.reisler. (b) (6) >; Freire, Maria (FNIH)
[T] < (b) (6) Elsaid, Olivia < (b) (6) Appell, Evan < (b) (6)
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
Stacey, Mike, and Helen

-----Original Appointment-----
From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: https://secure-web.cisco (b) (6)
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 1/21/2021 3:57:00 AM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

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Subject: Master Protocol Development and Agent Prioritization Manuscripts for ACTIV TX-Clinical Comment

CONFIDENTIAL – DO NOT SHARE BEYOND GROUP

Dear ACTIV TX-Clinical WG,

As discussed on last week's call, I am now distributing the current 90% finalized drafts of the Master Protocol Development and Agent Prioritization manuscripts for this group's review and comment. Please find the manuscripts at these links:
Agent Prioritization:
https://docs.google.com/document/d/1w_wKs1_bX2E_pdfmcXvz-0qW2cMey0w0RqUu1wMU2vE/edit

Master Protocol Development:
https://docs.google.com/document/d/1nIZT4_rPR6v1lbtCEdnE2hUumo6BsiQu85dW7Pd0xGU/edit

We would ask that the team members here review the document to ensure that you feel it accurately reflects the process and efforts of this WG. ***We would ask that the group focus on any major comments that you feel are "critical" to the manuscript. We would ask that you not wordsmith or refine for style at this point, as each of these documents have been through about ~10 of your colleagues for drafting, review, and refinement.***

If you do have suggestions, please follow the instructions at the top of the Google document in green to turn on suggestions in the document before you edit. **If you do choose to comment, please ensure that you have all suggestions returned by a week from today on Wednesday, January 27th at 5pm ET.**

Finally, we would ask that you do not share these manuscripts with anyone outside of this distribution list at this time. They are still in draft phase and confidential, so we do not wish to hurt our chance of publication by having them made public to early and in their unfinished form.

Thank you in advance for your assistance with this effort.

Kind regards,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 5/30/2020 2:39:33 AM

To: Jim Neaton [(b) (6) Jens Lundgren (b) (6) Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [(b) (6) William Erhardt [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; d13smith@ucsd.edu; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Eron, Joe [(b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]

CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6) Eron, Joseph J Jr (b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Chen, Helen Q. [(b) (6)

Subject: Joint ACTIV-2 and ACTIV-3 Writing Team Meeting

Location: https://fnih.zoom.us/j (b) (6)

Start: 6/4/2020 4:00:00 PM

End: 6/4/2020 5:00:00 PM

Show Time As: Tentative

Required Attendees:	Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]
Optional Attendees:	Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/30/2020 1:22:11 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Gee, no pressure.

From: Collins, Francis (NIH/OD) [E] < (b) (6)
Sent: Friday, May 29, 2020 7:50 PM
To: Wholley, David (FNIH) [T] < (b) (6)
Cc: Adam, Stacey (FNIH) [T] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Gonzalez, Nina < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6)
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Many thanks. I await the masterpiece.

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Friday, May 29, 2020 7:41 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] (b) (6) ; Freire, Maria (FNIH) [T] (b) (6) ; Gonzalez, Nina (b) (6) ; Parker, Ashley (NIH/OD) [E] (>; Freire, Maria (FNIH) [T] b
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Friday, May 29, 2020 5:59 PM
To: Wholley, David (FNIH) [T] (b) (6)
Cc: Adam, Stacey (FNIH) [T] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Gonzalez, Nina (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I

have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] (b) (6)
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Gonzalez, Nina (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:
Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a ***portfolio*** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
    - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
    - ACTIV hiVIG (sponsored by NIAID) - in progress
    - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
    - ACTIV-2*– Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
    - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
    - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
    - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August *(if needed; i.e. if agents are not incorporated into mAb protocols)*
      * current priority
      [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
  [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Proritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators

- Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
- 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
- All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
- Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
- Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
- Protocol is 80% complete
    - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
        - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
    - All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)

- "ACTIV-4" Protocol for anticoagulants
    - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS "network of networks" with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
on behalf of Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/17/2021 12:03:01 AM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Reed, John (b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6)]; Virgin,

Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6)

CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; FNIH Central Account [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Dally, Nicolle [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Tolman, Brett [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]

Subject: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021

Attachments: 02.17.21 ACTIV EC and Leadership Team Meeting 20210216_vF.pdf; 02.17.21 ACTIV EC and Leadership Team Meeting_APPENDIX_20210216_vF.pdf; 2021-01-14_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.pdf

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time**. The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

Join Zoom Meeting
https://fnih.zoom.us/ (b) (6)

Meeting ID: (b) (6)
Passcode: (b) (6)
One tap mobile
(b) (6) US (Washington D.C)
US (Chicago)

Dial by your location
(b) (6) US (Washington D.C)
US (Chicago)
US (New York)
US (San Jose)
US (San Jose)
US (Tacoma)
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Meeting ID: (b) (6)
Passcode: (b) (6)
Find your local number: https://fnih.zoom.us (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [Srinivas. (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; I (b) (6) (b) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha

(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [(b) (6) Mason, Stephen [Stephen. (b) (6) (b) (6) Connelly, Sarah [(b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [(b) (6)]; (b) (6) (b) (6) .com; Diamond, Michael [(b) (6)

Start: 12/23/2020 3:00:00 PM
End: 12/23/2020 4:00:00 PM

Recurrence: (none)

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 9/25/2020 4:57:23 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [coll (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [(b) (6)]; Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6)]; Pao, William [wi (b) (6) Plump, Andrew [(b) (6) Stoffels, Paul [PStoffe4@its.jnj.com]; Woodcock, Janet (FDA/CDER) [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Desrosiers, Betsy [(b) (6) ; Young, John (b) (6)
CC: Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen Q. [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6)]; Mendelson, Jesse (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Santos, Michael (FNIH) [T] [(b) (6) Stratton, Benjamin [(b) (6)]; btolman [(b) (6) Tountas, Karen (FNIH) [T] (b) (6) Wachtel, Jonathan (b) (6) ; Wholley, David (FNIH) [T] (b) (6) ; Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] (b) (6) ; Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; McManus, Ayanna (NIH/OD) [E] [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Burklow, John (NIH/OD) [E] [(b) (6) ih.gov]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) FNIH Central Account [(b) (6) Freire, Maria (FNIH) [T] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) ih.gov]; Hallett, Adrienne (NIH/OD) [E] [adrienne.hal (b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) .gov]; Myles, Renate (NIH/OD) [E] [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [cynd (b) (6) Carver, Trea (NIH) [C] (b) (6) Hughes, Karen (NIH/OD) [E] (b) (6)]; Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; Sepulveda, Dorina (FNIH) [T] (b) (6) Simon, Dina (NIH/OD) [C] [(b) (6)]; Tajalli, Ada (NIH/OD) [E] [(b) (6)]; Gorman, Greta (FNIH) [T] [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6)]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Sorosa, Alex [(b) (6) Connelly, Sarah [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Riccobene, Kim [(b) (6) .com]; Hamilton, Nancy [(b) (6)

Subject: ACTIV EC & Working Group Co-Chair Meeting
Location: https://fnih.zoom.us/ (b) (6)

Start: 11/4/2020 3:00:00 PM
End: 11/4/2020 4:00:00 PM
Show Time As: Busy

Required Attendees: Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John
Optional Attendees: Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Appell, Evan; Chen, Helen; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett;

Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Freire, Maria (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hamilton, Nancy; Sorosa, Alex; Connelly, Sarah; Lowy, Douglas (NIH/NCI) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]

Sent: 10/22/2020 1:39:56 PM

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) (CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio (b) (6) ; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [rmdaigle@tulane.edu]; Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6)

Subject: Re: ACTIV Preclinical full working group

ACTIV Preclinical WG –

Results below for NGS at BEI for several different cell lines for SARS-CoV-2.

BLUF:

1) Recommend to relax the lot release criteria for (b) (4) .
2) Recommend to the (b) (4)
3) (b) (4) as they are not amendable to scaled production. They grow to slow and in patches, making it difficult to determine CPE.
4) (b) (4) as they didn't show any CPE, thus, knowing when to harvest is guess work.
5) Recommend selecting (b) (4) for scale up with multiple production streams to mitigate chances of unacceptable lots.

(b) (4)

(b) (4)

Thanks!

Clint Florence, Ph.D.
Program Officer, Office of Biodefense, Research Resources, and Translational Research
NIH/NIAID/DMID/OBRRTR/RRS
Room 8G56
5601 Fishers Lane
Rockville, MD 20852
Tel: (b) (6)
cell:

From: "Florence, Clint (NIH/NIAID) [E]" < (b) (6)
Date: Wednesday, October 21, 2020 at 12:47 PM
To: "Menetski, Joseph (FNIH) [T]" (b) (6) (b) (6)
< (b) (6) "kara. (b) (6) < (b) (6) "Hild, Sheri (NIH/OD)
[E]" < (b) (6) " (b) (6) < (b) (6)
" (b) (6) <Anna (b) (6) " (b) (6)
< (b) (6) " (b) (6) < (b) (6) "Baric, Ralph" < (b) (6)
" (b) (6) < (b) (6) "Ottinger, Elizabeth (NIH/NCATS [E]"
< (b) (6) "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) "Hewitt, Judith
(NIH/NIAID) [E]" < (b) (6) "Deming, Damon (FDA/CDER)" < (b) (6)
" (b) (6) < (b) (6) " (b) (6) < (b) (6)
" (b) (6) < (b) (6) "Parker, Ashley (NIH/OD) [E]"
< (b) (6) "Collins, Francis (NIH/OD) [E]" < (b) (6)
" (b) (6) < (b) (6) "Adams, Peter (OS/ASPR/BARDA)"
< (b) (6) "Rao, Srinivas" < (b) (6) "Qashu, Felicia (NIH/OD) [E]"
< (b) (6) Tomas Cihlar < (b) (6) "Pitt, Margaret L CIV USARMY MEDCOM
USAMRIID (USA)" < (b) (6) "Punturieri, Antonello (NIH/NHLBI) [E]"
< (b) (6) "Charette, Marc (NIH/NHLBI) [E]" < (b) (6) "Fessel, Josh
(NIH/NHLBI) [E]" < (b) (6) " (b) (6) < (b) (6)
" (b) (6) < (b) (6) " (b) (6)
< (b) (6) "Wholley, David (FNIH) [T]" < (b) (6) "Austin, Christopher (NIH/NCATS)

[E]" < (b) (6) "Melencio, Cheryl (FNIH) [T]" < (b) (6) "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) "Desrosiers, Betsy" < (b) (6) Eric Hughes < (b) (6) "Jansen, Kathrin" < (b) (6) "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) "Lowy, Douglas (NCI)" < (b) (6) "Read, Sarah (NIH/NIAID) [E]" < (b) (6) "Tountas, Karen (FNIH) [T]" < (b) (6) "Santos, Michael (FNIH) [T]" < (b) (6) "Adam, Stacey (FNIH) [T]" < (b) (6) "James, Stephanie (FNIH) [T]" < (b) (6) "Alvarez, Rosa Maria" < (b) (6) "Kim, Elizabeth" < (b) (6) btolman < (b) (6) "Wachtel, Jonathan" < (b) (6) Prabhavathi Fernandes < (b) (6) "Diamond, Michael" < (b) (6) Rose Li < (b) (6) Dana Carluccio < (b) (6) "Lagos, Enrique (NIH/NCATS) [E]" < (b) (6) "Jonson, Samantha (NIH/NCATS) [E]" < (b) (6) "Gonzalez, Nina" < (b) (6) "Simon, Dina (NIH/OD) [C]" < (b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" < (b) (6) "Rodriguez, Robin D" < (b) (6) Dave Frankowski < (b) (6) "Baric, Toni C" < (b) (6) "Lowy, Douglas (NIH/NCI) [E]" < (b) (6) "Florence, Clint (NIH/NIAID) [E]" < (b) (6) Nancy Haigwood < (b) (6) "Stratton, Benjamin" < (b) (6) "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) "Anderson, James (NIH/OD) [E]" < (b) (6) "Hawk, Harrison" < (b) (6) "Mason, Stephen" < (b) (6) "Connelly, Sarah" < (b) (6) " (b) (6) < (b) (6)

Subject: Re: ACTIV Preclinical full working group

ACTIV Preclinical Group –

(b) (4)

(b) (4)

Thanks –

Clint

From: (b) (6)
When: 10:15 AM - 11:00 AM October 21, 2020
Subject: ACTIV Preclinical full working group
Location: https://fnih.zoom.us (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
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Dial by your location
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US (Chicago)
US (New York)
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US (San Jose)
US (Tacoma)
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Meeting ID: (b) (6)
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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

Sent: 12/22/2020 4:47:51 PM

To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) (b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [(b) (6) (b) (6)

Subject: Canceled: ACTIV Preclinical full working group
Location: https://fnih.zoom.us/ (b) (6)

Start: 12/23/2020 3:00:00 PM
End: 12/23/2020 4:00:00 PM
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every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) (b) (6)

Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;

Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah; (b) (6) Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; (b) (6)

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CC: Elizabeth Kim [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6) Salathin, Carla [(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [Lucas.Smalldon@roseliassociates.com]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Materials for ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5
Attachments: 2020-04-28_TX_Clinical_WG_Agent_Prioritization_Sub-WG_Summary.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_04302020.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you all for all the hard work you all are doing right now for the agent scoring. I appreciate all the information sharing that has been happening today to allow others to see the compound information you have found. I look forward chatting with you tomorrow to address any questions you may need addressed before our discussion of the results on Friday.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer

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CC: Elizabeth Kim [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6) Salathin, Carla [(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon (b) (6) ; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Initial Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup #9
Attachments: ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 12May2020 Key Takeaways.pdf

Dear TX-Clinical Agent Prioritizaiton Subgroup,

Thank you so much for another meeting with great feedback to refine the process. Elizabeth and I will work to incorporate your additional changes to the scoring and weighting. In addition, I am looking into the additional resources that the group was requesting.

For now please find some high level action items and notes that Elizabeth was kind enough to capture. I will follow-up with the formal summary to the meeting in the next 24 hours or so.

As always, if you have any questions, please do not hesitate to contact us.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; LaVange, Lisa [(b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Levy, Elliot (b) (6) ; Garner, Carl (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Mellors, John W (b) (6)]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Draghia-Akli, Ruxandra [(b) (6) Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Kim, Elizabeth [(b) (6)

CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6); Tolman, Brett [(b) (6) Alvarez, Rosa (b) (6) Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200730.pdf

Start: 7/30/2020 5:00:00 PM
End: 7/30/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Levy, Elliot; Garner, Carl; Sizemore, Christine (NIH/FIC) [E]; Mellors, John; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn,

Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Freire, Maria (FNIH) [T]; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting. Contact me if you have any additional items for the agenda.

Thanks,
Stacey

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

Sent: 7/28/2020 6:58:21 PM

To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell ((b) (6) [(b) (6) (b) (6) Cavaleri Marco [(b) (6) (b) (6) (b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) (b) (6) Tal Zaks [(b) (6)

CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Paul Gillard [(b) (6) François P Roman [(b) (6) Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; 'Wachtel, Jonathan' [(b) (6) Stratton, Benjamin [(b) (6) Anderson, Margaret [(b) (6) (b) (6) (b) (6) Bethany Stokes [(b) (6) Kathleen Callahan [(b) (6) Molloy, Delia (DPH) [(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Jacqueline Miller [(b) (6) Kayvon Modjarrad (b) (6)

Subject: Agenda for tomorrow's (Wednesday's) Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 10am ET / 7am PT / 4pm CEST.

This week is the 16th of the Vaccines Working Group, and Francis Collins will join the start of tomorrow's meeting to recognize the progress we have made. Additionally, we have been asked by ACTIV leadership to consider how the Working Group should operate from here.

We are deeply grateful to all of you for your engagement in our collective efforts. We have identified and addressed many important topics for COVID-19 vaccine development and we have additional contributions yet to come, such as the article on vaccine-associated enhanced disease.

At this meeting we would like to discuss the topics that the group would prioritize going forward. We want to support the Working Group to continue to take on issues where we have unique value to add while adjusting the number and frequency of meetings to ensure we are being efficient with everyone's time.

Please come to the meeting with your perspective on what topics are important for the Working Group to address; in the immediate term we plan to continue conversations about the implications of the first vaccine success and of course continue with the dissemination of the vaccine-associated enhanced disease findings. **If you are unable to attend the meeting, as always your thoughts are welcome via email**.

Finally, we want to acknowledge and apologize for the overlap of tomorrow's meeting with the start of the ACIP meeting. We know some of you are directly involved with ACIP and will miss the Working Group meeting. Certainly we will wrap up as soon as our discussion is finished for those who would like to hop over to the ACIP meeting afterwards.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Saturday, July 25, 2020 5:01 PM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

Thank you for your participation in the meeting. The meeting notes and materials are attached.

We're also grateful for the feedback you have provided on the vaccine-associated enhanced disease manuscript. Ann and Bart are working through that now, and we look forward to submitting the final version soon.

We will be in touch again soon about this week's meeting (Wednesday, 10am ET), and in the meantime please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, July 21, 2020 10:05 PM
Subject: Agenda for the Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our meeting tomorrow (Wednesday), at 1:30pm ET (10:30am PT / 7:30pm CEST).

The agenda topics are:

- Brief update on the vaccine-associated enhanced disease manuscript
    - As a reminder, this is a product of the Working Group and all Working Group members are invited to provide feedback by Thursday at 8pm ET (see attached email sent by Brett on Monday)
- Follow-up discussion of approaches for non-specific immunity
    - Doug will lead this discussion. If you missed the discussion at last week's meeting, the notes are attached again.

As always, please let us know if you have any questions or input.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, July 19, 2020 4:04 PM
Subject: Notes from the Vaccines Working Group meeting

Dear Vaccines Working Group members,

Thank you for your participation in our last meeting, and particular thanks to Bob Gallo and Konstantin Chumakov and Paula for their presentations and discussion. Attached are the notes and slides presented.

As always, please don't hesitate to reach out with any comments or questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Friday, July 10, 2020 11:28 PM
Subject: Agenda for the Vaccines Working Group meeting Monday

Dear Vaccines Working Group members,

We're looking forward to our next meeting, Monday at 12pm ET (9am PT / 6pm CEST). There are two agenda topics for the meeting:

- The potential for OPV to provide temporary protection against COVID-19
    - Bob Gallo and colleagues will join to discuss their concept with the group
- A recap of the discussion Thursday in the Vaccines Clinical Trials Sub-Group meeting on the implications of the first vaccine licensure on other vaccine efficacy trials

As inputs to those conversations, the notes from the Clinical Trials Sub-Group meeting are attached along with two press articles and a compendium of journal articles about the OPV concept.

Please don't hesitate to reach out with any questions or feedback.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Timothy Burgess [(b) (6) Bozzette, Sam (NIH/NCATS) [E] (b) (6)]; Butterton, Joan (b) (6) De Claro, R. Angelo (FDA/CDER) [(b) (6)]; Draghia-Akli, Ruxandra [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [(b) (6)]; Judy Currier [(b) (6) Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [(b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6) Collins, Sylva (FDA/CDER) [(b) (6)]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6) .gov]; Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]; Reineck, Lora (NIH/NHLBI) [E] [(b) (6)]; Aggarwal, Neil (NIH/NHLBI) [E] [neil. (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Brown, Jeremy (NIH/NINDS) [E] (b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6)]; Culp, Michelle (NIH/OD) [E] [(b) (6) Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [(b) (6) .gov]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL (b) (6) ; (b) (6) Sizemore, Christine (NIH/FIC) [E] [(b) (6) Larry Tsai [(b) (6) Wung, Peter K [(b) (6) Davey Smith [(b) (6) Garner, Carl [(b) (6)

CC: Chen, Helen Q. [(b) (6) Sorosa, Alex David [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [(b) (6)]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] (b) (6)]; Salathin, Carla [(b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Dana Carluccio [dana. (b) (6) Rose Li Central Account [FN (b) (6) Lucas Smalldon [Lucas.Smal (b) (6) (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [felicia. (b) (6)]; Patterson, Amy (NIH/NHLBI) [E] [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6)]; Marston, Hilary (NIH/NIAID) [E] [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [(b) (6) Groesch, Mary (NIH/NHLBI) [E] [(b) (6) Shipp, Allan (NIH/NHLBI) [E] [allan. (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E] [(b) (6)]; Hone, David M (Dave) CIV DTRA J9 (USA) (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Walker, Paula (NIH/NINDS) [E] [(b) (6)]; Lumsden, Joanne (NIH/NCATS) [C] [(b) (6) Lerner, Andrea (NIH/NIAID) [E] (b) (6)]; Embry, Alan (NIH/NIAID) [E] [(b) (6) .gov]; Dally, Nicolle [(b) (6) Reich, Colleen [(b) (6)

Start: 4/15/2021 5:00:00 PM
End: 4/15/2021 6:00:00 PM

Recurrence: (none)

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (david.goff@nih.gov); Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner;

Optional Attendees:	Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K; Davey Smith Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Dally, Nicolle; Reich, Colleen

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

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Subject: RE: ACTIV Preclinical full working group

Attachments: 2020-09-09_Preclinical_WG_Summary_final.docx; Criteria to trigger discussion on adding a reference strain recommendation.pptx

Dear All,

Please find the minutes from this weeks full working group meeting. As requested, I am also attaching the most recent final version of the criteria to trigger review of a new virus strain to add as a reference stock.

Thank you all for all that you continue to do for this effort.

Best regards,
Joe

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

Sent: 8/18/2020 2:53:18 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [(b) (6) Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [(b) (6) Erck, Stan [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Pandya, Hitesh [hitesh. (b) (6) Pao, William (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) ; Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Rachel Ramoni [(b) (6) Reed, John (b) (6) Reese, David [(b) (6)]; Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) (b) (6) ; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Anderson, James (NIH/OD) [E] (b) (6) Burklow, John (NIH/OD) [E] [(b) (6) .gov]; Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) .gov]; Wolinetz, Carrie (NIH/OD) [E] [(b) (6)]; Bugin, Kevin (FDA/CDER) [Kevin. (b) (6) Bancel, Stephane [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John (b) (6) Pangalos, Mene [(b) (6) Paul, Steve [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6) Tsai, John (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

CC: Austin, Sarah (NIH/NIAID) [E] [(b) (6)]; Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Bell, Julie [(b) (6) Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara (b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E] | (b) (6) Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann (b) (6) Riccobene, Kim [(b) (6) Riggin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Suhana, Tina (NIH/VRC) [E] [(b) (6)]; Thomas, Ashley (FDA/CDER) | (b) (6)]; Wood, Gretchen (NIH/OD) [E] [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6) Underwood, Nancy [(b) (6) Zottoli, Jessica [Jessica. (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Trea (NIH) [C] [(b) (6) Hughes, Karen (NIH/OD) [E] [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Tajalli, Ada (NIH/OD) [E] [(b) (6)]; Gorman, Greta (FNIH) [T] [(b) (6)

Meltzer, Abbey (FNIH) [T] [(b) (6) Regan, Donna M [donna. (b) (6) Lucas Smalldon [(b) (6) Alvarez, Rosa Maria [(b) (6) Gonzalez, Nina [(b) (6) Appell, Evan [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen Q. [(b) (6) Hawk, Harrison [(b) (6) Stratton, Benjamin [(b) (6) btolman [(b) (6) Tountas, Karen (FNIH) [T] (b) (6) Wachtel, Jonathan [(b) (6) Dana Carluccio [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) h.gov]; John Lepore [(b) (6) Huang, Grant [(b) (6) Hamilton, Nancy [(b) (6) Elsaid, Olivia [(b) (6)

Subject: ACTIV Leadership Call #8
Location: https://fnih.zoom.us/j, (b) (6)

Start: 9/23/2020 1:00:00 PM
End: 9/23/2020 2:00:00 PM
Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Bugin, Kevin (FDA/CDER)

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggin, Mary; Ripley, Nadege; Schuster, Donna; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Regan, Donna M; Hamilton, Nancy; Lucas Smalldon; Alvarez, Rosa Maria; Gonzalez, Nina; Appell, Evan; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Hawk, Harrison; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Dana Carluccio; Lowy, Douglas (NIH/NCI) [E]; John Lepore; Huang, Grant

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From: Appell, Evan [(b) (6)
Sent: 11/12/2020 7:27:37 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner

[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201112_vF.pdf

Hi All,

Thank you for joining our Therapeutics-Clinical Working Group meeting this afternoon. Please see attached for the materials we reviewed during our call, and let us know if you have any questions or feedback.

Best,
Evan

Evan Appell
Deloitte Consulting LLP
Mobile: (b) (6)
(b) (6)

-----Original Appointment-----
From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Monday, August 31, 2020 10:34 AM
To: Adam, Stacey (FNIH) [T]; Appell, Evan; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) ; Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, November 12, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom. (b) (6)

-----Original Appointment-----
From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) ; Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;

Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Occurs every Thursday effective 6/25/2020 until 12/31/2020 from 1:00 PM to 2:00 PM Eastern Standard Time.
Where: https://fnih.zoom.us (b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/16/2020 12:48:23 PM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish (b) (6)]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Rose Li [(b) (6) Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6)

Subject: Materials for ACTIV Therapeutics-Clinical Working Group Meeting #2

Attachments: ACTIV Therapeutics-Clinical WG Meeting Agenda_04152020.pdf; ACTIV Therapeutics-Clinical WG 16Apr2020 Meeting Guide 04152020.pdf; 2020-04-14_TX-Clinical_WG_Agent_Prioritization_Subgroup_Summary.pdf; ACTIVPrioritizationCriteria-v2.xlsx; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 1_Key Takeaways_04152020v2.docx

Dear COVID PPP Therapeutics-Clinical WG Members and Co-Chairs from other WGs,

Thank you all for all your hard work this week. We cannot thank you enough for you time and dedication to this important effort. Today's large group meeting will serve for the two subgroups to come back together and provide updates to each other and ensure we are staying on a unified path to move forward for this workstream.

Please find attached the materials for today's meeting:

1. Agenda
2. Slides for the presentation
3. Formal summary for Agent Prioritization Subgroup – 1st Meeting
4. Draft Agent Prioritization Criteria/Data Needed (Excel Sheet)
5. High Level summary and action items for the Master Protocol Subgroup – 1st Meeting

Note: The Master Protocol Subgroup will be having a second meeting immediately before this meeting, so we may be updating their summary slides on the fly during the meeting. Thank you for you patience and understanding with this fast moving process.

Reminder #1: If you are part of the Agent Prioritization Subgroup, we would like your feedback on the criteria in the Excel Spreadsheet attached.
Reminder #2: If you have not already done so, please fill out this Doodle Poll with your availability.
https://doodle.com/poll/nhd5zgimn537qqk5
Agent Prioritization Subgroup we especially need you to fill out for tomorrow as soon as you can.

If you have any questions, please do not hesitate to reach out.

Kind regards,
Stacey, on Behalf of the TX-Clinical WG

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

Sent: Sunday, April 12, 2020 1:50 PM
When: Thursday, April 16, 2020 12:00 PM-1:30 PM America/New_York.
Where: https://zoom (b) (6)

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From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]

Sent: 7/1/2020 3:39:02 PM

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel,

Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6)]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; (b) (6) Diamond, Michael [(b) (6)

Subject: Re: ACTIV Preclinical full working group
Attachments: 2020.06.20.137687v1.full.pdf

All –

U PITT's pre-print in YOUNG AGMs utilizes the Munich strain which I believe has the D614 mutant.

In their hands, they didn't report any dramatic increase in pathogenesis with the assays they implemented.

Might be of benefit in the EXE meeting tonight.

Just an FYI.

Clint

From: (b) (6)
When: 10:00 AM - 11:00 AM July 1, 2020
Subject: ACTIV Preclinical full working group
Location: https://fnih.zoom.us/ (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/24/2020 12:30:30 AM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6)

CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [(b) (6)

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_24Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting #7 Agenda_04222020.pdf; Drug-info-COVID-19-Visante-4-21.pdf

Location: https://fnih.zoom. (b) (6)

Start: 4/24/2020 2:00:00 PM

End: 4/24/2020 3:00:00 PM

Show Time As: Tentative

Required Attendees:	Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael
Optional Attendees:	Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US; Qashu, Felicia (NIH/OD) [E]; Stratton, Benjamin

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

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From: Pangalos, Mene [(b) (6)
Sent: 6/5/2020 3:04:08 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: combinatorics and monoclonal Abs - Data Shared In Confidence

Flag: Follow up

Francis,

I would be happy to put ours in to this approach.. we are taking this approach in the UK too. I don't know if others will be happy to do but I do think it will be useful and instructive for you/NIH to know which antibodies combine best with which. We did synergy experiments on about 15 of our mAbs and there were clear differences in which ones combined well.

Mene

Sir Menelas N Pangalos PhD FRSB FMedSci
EVP and President BioPharmaceuticals R&D
AstraZeneca, Melbourn Science Park,
Cambridge Road, Royston, Herts SG8 6EE

Work: (b) (6)
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On 5 Jun 2020, at 15:57, Collins, Francis (NIH/OD) [E] < (b) (6) wrote:

Thanks, Mene, this example is very instructive. I was imaging conducting this kind of assessment of synergism using viral neutralization and limiting dilutions, but it's great to see real data. Per your request, I will keep this information to myself.

What would you say to the idea of organizing a binary comparison like this of all of the mAbs that are ready for trials in the next couple of months? This could be done in an independent lab (NIH's BSL-3 lab would be happy to set this up), with data available to all participants.

Best, Francis

From: Pangalos, Mene < (b) (6)
Sent: Friday, June 5, 2020 6:55 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6)
Cc: Esser, Mark < (b) (6) Villafana, Tonya < (b) (6)
Subject: RE: combinatorics and monoclonal Abs - Data Shared In Confidence

Francis,

We do these assays ourselves and with collaborators... they are often done in oncology as I am sure you know. This is data from two of our mAbs that demonstrated what we are looking for.

Please do not share this data set as is yet to be published and I am sharing in confidence but hopefully gives you a sense of what we do and what we hope to observe. Our cocktail moving forward will take the two mAbs with the best synergistic effect in neut assays into the clinic (which we have in fact already selected).

These sorts of assays could be used to test a variety of antibodies from different sources to find combinations that work and will be important if resistance emerges.

Mene

mAb [redacted] (ng/mL) →

mAb [redacted] (ng/mL) ↓		250	125	62.5	31.3	15.6	7.8	3.9	2	1	0
		1	2	3	4	5	6	7	8	9	10
250	A	100	100	100	100	100	99	99	95	94	96
125	B	100	100	100	100	100	95	94	85	83	81
63	C	100	100	100	99	96	93	64	29	10	0
31	D	100	100	99	99	90	66	4	0	0	0
16	E	100	100	99	97	83	30	0	0	0	0
8	F	100	99	98	91	66	0	0	0	0	0
4	G	100	99	93	75	46	0	0	0	0	0
0	H	97	91	83	46	6	0	0	0	0	0

Sir Menelas N Pangalos PhD FRSB FMedSci
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http://openinnovation.astrazeneca.com

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: 05 June 2020 02:26
To: Pangalos, Mene (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6)
Subject: combinatorics and monoclonal Abs

Hi Mene,

I think I heard you say something during the ACTIV call yesterday about ways to optimize the choice of mAbs that would be synergistic. For the upcoming inpatient and outpatient trials of mAbs against SARS-CoV-2, it would be great to have available a preclinical in vitro assay that could predict that kind of synergy in vivo. Do you have an approach that you or someone on your staff would be willing to tell me about?

Best, Francis

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CC: Mason, Stephen [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Start: 8/19/2020 2:00:00 PM
End: 8/19/2020 3:00:00 PM

Recurrence: (none)

Required Attendees: (b) (6) Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) Annaliesa. (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) rbaric@email.unc.edu; (b) (6) ; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Optional Attendees: Mason, Stephen; Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; (b) (6) Gilliland, Taylor (NIH/OD) [E]

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/4/2020 3:29:51 AM
To: (b) (6) (b) (6) (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; (b) (6) (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Bett, Andrew J [(b) (6) Gilbert PhD, Peter B [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Greg Glenn [(b) (6) Cavaleri Marco [(b) (6) Kelly, Beth [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) (b) (6) (b) (6) Jeneffer Haynes [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brian Rosen [(b) (6) Cheryl Keech [(b) (6)
Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting
Attachments: 2020-06-02 Protective Immune Responses Sub-Group meeting Notes.docx

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Monday, June 1, 2020 1:04 PM
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
  - Develop specifics of what we are looking for from immunology research
  - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
  - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
  - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

---

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
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From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]

Sent: 9/2/2020 9:23:25 PM

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) (b) (6) Reynolds, Lindsey [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]

Subject: Re: ACTIV Preclinical full working group

All –

(b) (4)

Clint

From: (b) (6)
When: 10:00 AM - 11:00 AM September 2, 2020

Subject: ACTIV Preclinical full working group
Location: https://fnih.zoom.us (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
https://fnih.zoom.us (b) (6)

Meeting ID: (b) (6)
Passcode: (b) (6)
One tap mobile
(b) (6) US (Germantown)
US (Chicago)

Dial by your location
(b) (6) US (Germantown)
US (Chicago)
US (New York)
US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)
Meeting ID: (b) (6)
Passcode: (b) (6)
Find your local number: https://fnih.zoom.us (b) (6)

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 8/14/2020 5:03:43 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTIV website updates per EC slides/meeting today

Great. And FC is proposing that the talk about a label of 'ACTIV-associated trials" for things that ACTIV partner companies are pursuing but aren't technically ACTIV trials (not following an ACTIV master protocol, I guess). This would probably apply to IVIG trials (hyper immune globulin from patients). Reaction seemed positive.

From: Brodd, Lauren (NIH/OD) [E] < (b) (6)
Sent: Friday, August 14, 2020 12:35 PM
To: Gadbois, Ellen (NIH/OD) [E] < (b) (6)
Subject: RE: ACTIV website updates per EC slides/meeting today

Hi Ellen,

Thanks for flagging! Ashley and I have been working with Renate and her team to revise the website to provide more detailed information about each of the working groups. In the updated version, we include language about the clinical trial capacity group being finished as of 7/31 and the vaccines group now only meeting on an ad hoc basis. Not sure the exact timeline (FNIH is currently reviewing the drafts) but those groups will be addressed when the updated version goes live.

Thanks,
Lauren

From: Gadbois, Ellen (NIH/OD) [E] (b) (6)
Sent: Friday, August 14, 2020 12:18 PM
To: Brodd, Lauren (NIH/OD) [E] < (b) (6)
Subject: ACTIV website updates per EC slides/meeting today
Importance: High

You may want to revise how the working groups are listed on the website since clinical trials capacity is done, and vaccine is suspended (may be reconvened if needed)—see slides.

From: Melencio, Cheryl (FNIH) [T] < (b) (6) **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Thursday, August 13, 2020 10:20 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) ; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) ; Dolsten, Mikael (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E] (b) (6) >; Marks, Peter (FDA/CBER) (b) (6) >; Pao, William (b) (6) ; Plump, Andrew < (b) (6) >; Stoffels, Paul (b) (6) ; Woodcock, Janet (FDA/CDER) < (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) >; Desrosiers, Betsy (b) (6) >; Eric Hughes < (b) (6) >; Jansen, Kathrin < (b) (6) >; Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Young, John < (b) (6) ; Wholley, David (FNIH) [T] < (b) (6)
Cc: Anderson, James (NIH/OD) [E] < (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6) Burklow, John (NIH/OD) [E] (b) (6) >; Castillejos, Carlos (b) (6) >; Culp, Michelle (NIH/OD) [E] (b) (6) FNIH Central Account < (b) (6) Freire, Maria

(FNIH) [T] (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) ; Hallett, Adrienne (NIH/OD) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) Myles, Renate (NIH/OD) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E] (Wolinetz, Carrie (NIH/OD) [E] (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) ; Alvarez, Rosa < (b) (6) Anderson, Margaret (b) (6) ; Chen, Helen (b) (6) >; Elsaid, Olivia (b) (6) ; Gonzalez, Nina (b) (6) Hawk, Harrison < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Stratton, Benjamin (b) (6) >; Tolman, Brett (b) (6) Tountas, Karen (FNIH) [T] (b) (6) Wachtel, Jonathan < (b) (6)

Subject: Materials for August 14 ACTIV Executive Committee Teleconference
Importance: High

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **12:00 – 1:00 PM Eastern U.S. time** tomorrow, Friday, August 14. I have also attached notes from our July 29 Leadership Team meeting as well as our last EC meeting on July 15. As you know we will be hearing from two Working Groups instead of four, **so the co-chairs have decided to make this call as well as future EC and LT calls going forward 60 minutes in length instead of 90 minutes.**

The Zoom information is:
Join Zoom Meeting
https://fnih.zoom. (b) (6)

Meeting ID: (b) (6)
Passcode: (b) (6)
One tap mobile
(b) (6) US (Germantown)
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Dial by your location
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Meeting ID: (b) (6)
Passcode: (b) (6)
Find your local number: https://fnih.zoom. (b) (6)

Please let Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 1/18/2021 11:11:35 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: Fwd: ACTIV Leadership/EC Call #12
Attachments: 2021-01-14_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.pdf; ATT00001.htm

FYI

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: (b) (6) .

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" (b) (6)
Date: January 17, 2021 at 12:18:46 PM EST
To: "Melencio, Cheryl (FNIH) [T]" < (b) (6) "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) "Carter, Kara" < (b) (6) "Cavalcri, Marco" (b) (6) >, "Cihlar, Tomas" < (b) (6) "Collins, Francis (NIH/OD) [E]" (b) (6) >, "Corey, Larry" (b) (6) >, "Culp, Michelle (NIH/OD) [E]" (b) (6) Victoria Davey (b) (6) , "Disbrow, Gary (OS/ASPR/BARDA)" (b) (6) , "Dolsten, Mikael" < (b) (6) "Erbelding, Emily (NIH/NIAID) [E]" (b) (6) >, "Erck, Stan" (b) (6) >, "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) "Gibbons, Gary (NIH/NHLBI) [E]" < (b) (6) "Hudson, Thomas" (b) (6) , "James, Stephanie (FNIH) [T]" (b) (6) "Johnson, Robert (OS/ASPR/BARDA)" (b) (6) , "Kramer, Lynn" (b) (6) "Lane, Cliff (NIH/NIAID) [E]" < (b) (6) "Marks, Peter (FDA/CBER)" < (b) (6) , "Marston, Hilary (NIH/NIAID) [E]" (b) (6) , "Mascola, John (NIH/VRC) [E]" < (b) (6) "Meeker, David" < (b) (6) "Menetski, Joseph (FNIH) [T]" < (b) (6) "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" (b) (6) , "Pandya, Hitesh" (b) (6) >, "Pao, William" (b) (6) >, "Parker, Ashley (NIH/OD) [E]" (b) (6) , "Perlmutter, Roger" <r (b) (6) >, "Plenge, Robert" (b) (6) "Plump, Andy" (b) (6) "Rouse, Doris" < (b) (6) "Santos, Michael (FNIH) [T]" (b) (6) , "Skovronsky, Daniel" (b) (6) "Stein, Peter (FDA/CDER)" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Talley, Michael" (b) (6) , "Tsai, John" (b) (6) >, "Vessey, Rupert" (b) (6) , "Virgin, Skip" < (b) (6) "Woodcock, Janet (FDA/CDER)" < (b) (6) "Young, John" <j (b) (6) , "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) Eric Hughes (b) (6) >, "Jansen, Kathrin" (b) (6) >, "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) "Lowy, Douglas (NCI)" < (b) (6) "Read, Sarah (NIH/NIAID) [E]" (b) (6) , "Adam, Stacey (FNIH) [T]" < (b) (6) Margaret Anderson < (b) (6) "Appell, Evan" < (b) (6) "Chen, Helen" < (b) (6) "Connelly, Sarah"

(b) (6) >, "Gonzalez, Nina" < (b) (6) "Hawk, Harrison" < (b) (6) "Mendelson, Jesse" (b) (6) >, "Nasr, Hana" (b) (6) "Sorosa, Alex" (b) (6) >, "Stratton, Benjamin" < (b) (6) btolman < (b) (6) "Tountas, Karen (FNIH) [T]" (b) (6) "Wachtel, Jonathan" (b) (6) >, "Anderson, James (NIH/OD) [E]" < (b) (6) "Burklow, John (NIH/OD) [E]" < (b) (6) "Carluccio, Dana" < (b) (6) "Castillejos, Carlos" < (b) (6) FNIH Central Account < (b) (6) "Hallett, Adrienne (NIH/OD) [E]" < (b) (6) "Myles, Renate (NIH/OD) [E]" (b) (6) , "Wolinetz, Carrie (NIH/OD) [E]" (b) (6) >, "Meltzer, Abbey (FNIH) [T]" (b) (6) , "Esser, Mark" < (b) (6) "Bancel, Stephane" (b) (6) , "Fauci, Anthony (NIH/NIAID) [E]" (b) (6) , "Lepore, John" (b) (6) "Pangalos, Mene" < (b) (6) "Paul, Steve" (b) (6) >, Rachel Ramoni < (b) (6) "Reed, John" < (b) (6) "Reese, David" < (b) (6) "Stoffels, Paul" (b) (6) "Desrosiers, Betsy" (b) (6)

Cc: "Austin, Sarah (NIH/NIAID) [E]" < (b) (6) v>, "Barasch, Kimberly (NIH/NIAID) [C]" (b) (6) >, "Burrus-Shaw, Cyndi (NIH/OD) [E]" (b) (6) >, "Carver, Trea (NIH) [C]" (b) (6) , "Caulfied, Anita" < (b) (6) "Coan, Amanda" (b) (6) >, "Conrad, Patricia (NIH/NIAID) [E]" (b) (6) >, "Dimishkov, Roxanne (NIH/NHLBI) [C]" (b) (6) "Edl, Susan" (b) (6) , "Fuhrer, Nicole" (b) (6) >, "Giorgi, Sara" < (b) (6) "Hoffstetter, Renata (FNIH) [T]" < (b) (6) "Iberdemaj, Vaide" < (b) (6) "Jenkins, Christine S." (b) (6) >, "Lagos, Enrique (NIH/NCATS) [E]" < (b) (6) >, "Lever, Susan" < (b) (6) "Martin, Melisa" < (b) (6) "McManus, Ayanna (NIH/OD) [E]" < (b) (6) , "Minnich, Beth" (b) (6) >, "Perala, Mie" (b) (6) , "Protasiewicz, Ann" (b) (6) >, "Riccobene, Kim" < (b) (6) "Riggin, Mary" < (b) (6) "Ripley, Nadege" < (b) (6) "Schuster, Donna" < (b) (6) "Sepulveda, Dorina (FNIH) [T]" < (b) (6) "Simon, Dina (NIH/OD) [C]" < (b) (6) "Suhana, Tina (NIH/VRC) [E]" (b) (6) "Thomas, Ashley (FDA/CDER)" < (b) (6) "Wood, Gretchen (NIH/OD) [E]" <w (b) (6) ov>, "Togashi, Micko (NIH/NCI) [E]" < (b) (6) >, "Underwood, Nancy" <nancy (b) (6) "Zottoli, Jessica" < (b) (6) "Hughes, Karen (NIH/OD) [E]" < (b) (6) , "Tajalli, Ada (NIH/OD) [E]" (b) (6) >, "Regan, Donna M" (b) (6) , "Magbie-Robinson, Kim (NIH/OD) [C]" (b) (6) , "Vessey, Rupert" (b) (6) "Lowy, Douglas (NIH/NCI) [E]" < (b) (6) "Lumsden, Joanne (NIH/NCATS) [C]" (b) (6) , "Ellis, Carol" (b) (6) , "Bell, Julie" (b) (6) "Hoban, Michelle" (b) (6) , "Melencio, Cheryl (FNIH) [T]" (b) (6)

Subject: RE: ACTIV Leadership/EC Call #12

Dear ACTIV Executive Committee and Leadership Team members, and meeting attendees:

Attached please see the minutes from our meeting this past Thursday, January 14, 2021. As always please let me know if you have any additional comments or questions.

Regards,
David Wholley

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/20/2021 10:00:33 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, January 14, 2021

Flag: Follow up

Just fyi, just got this.

From: Reed, John /US < (b) (6)
Sent: Wednesday, January 20, 2021 3:47 PM
To: Wholley, David (FNIH) [T] < (b) (6)
Subject: Re: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, January 14, 2021

David: Sorry I missed the meeting due to an unavoidable conflict. Best, John

---

From: "Melencio, Cheryl (FNIH) [T]" (b) (6) (6) on behalf of "Wholley, David (FNIH) [T]" < (b) (6)
Date: Wednesday, January 13, 2021 at 10:38 AM
To: "Austin, Christopher (NIH/NCATS) [E]" (b) (6) >, Stephane Bancel (b) (6) >, "Carter, Kara" <(b , "Cavaleri, Marco" (b) (6) >, "Cihlar, Tomas" (b) (6) 6) , "Collins, Francis (NIH/OD) [E]" (b) (6) >, "Corey, Larry" (b) (6) , "Culp, Michelle (NIH/OD) [E]" (b) (6) , Victoria Davey (b) (6) , "Disbrow, Gary (OS/ASPR/BARDA)" (b) (6) , "Dolsten, Mikael" (b) (6) >, "Erbelding, Emily (NIH/NIAID) [E]" (b) (6)) (6) , "Erck, Stan" < (b) (6) , "Fauci, Anthony (NIH/NIAID) [E]" (b) (6) b) (6) "Freire, Maria (FNIH) [T]" < (b) (6) , "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) , "Gibbons, Gary (NIH/NHLBI) [E]" < (b) (6) "Hudson, Thomas" (b) (6) >, "James, Stephanie (FNIH) [T]" (b) (6)) (6) "Johnson, Robert (OS/ASPR/BARDA)" < (b) (6) , "Kramer, Lynn" (b "Lane, Cliff (NIH/NIAID) [E]" (b) (6) "Lepore, John" (b) (6)) Peter Marks (b) (6) >, "Marston, Hilary (NIH/NIAID) [E]" < (b) (6) >, "Mascola, John (NIH/VRC) [E]" <j (b) (6) "Meeker, David" < (b) (6) "Menetski, Joseph (FNIH) [T]" < (b) (6) rg>, "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" < (b) (6) , "Pandya, Hitesh" < (b) (6) , "Pangalos, Mene" (b) (6) >, "Pao, William" <wil (b) (6) "Parker, Ashley (NIH/OD) [E]" (b) (6)) (6) "Paul, Steve" < (b) (6) , "Perlmutter, Roger" < (b) (6) "Plenge, Robert" < (b) (6) , "Plump, Andy" <a (b) (6) Rachel Ramoni < (b) (6) , John /US Reed < (b) (6) , "Reese, David" < (b) (6) "Rouse, Doris" < (b) (6) , "Santos, Michael (FNIH) [T]" (b) (6) "Skovronsky, Daniel" (b) (6) (6) , "Stein, Peter (FDA/CDER)" < (b) (6) Paul Stoffels < (b) (6) , "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) , "Talley, Michael" <michael.j.tal (b) (6) , "Tsai, John" < (b) (6) , "Vessey, Rupert" < (b) (6) "Virgin, Skip" (b) (6) "Wholley, David (FNIH) [T]" (b) (6) "Woodcock, Janet (FDA/CDER)" < (b) (6) "Young, John" < (b) (6) , "Colvis, Christine (NIH/NCATS) [E]" (b) (6) "Desrosiers, Betsy" (b) (6) , Eric Hughes < (b) (6) "Jansen, Kathrin"

(b) (6) , "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) (b) (6) , "Lowy, Douglas (NCI)" < (b) (6) , "Read, Sarah (NIH/NIAID) [E]" (b) (6) , "Young, John" < (b) (6) , "Adam, Stacey (FNIH) [T]" < (b) (6) , Margaret Anderson (b) (6) (b) (6) , "Appell, Evan" < (b) (6) , "Chen, Helen" < (b) (6) , "Connelly, Sarah" < (b) (6) "Gonzalez, Nina" < (b) (6) , "Hawk, Harrison" < (b) (6) "Mendelson, Jesse" < (b) (6) , "Menetski, Joseph (FNIH) [T]" < (b) (6) , "Nasr, Hana" < (b) (6) , "Santos, Michael (FNIH) [T]" < (b) (6) , "Sorosa, Alex" (b) (6) >, "Stratton, Benjamin" (b) (6) >, btolman (b) (6) , "Wachtel, Jonathan" (b) (6) , "Wholley, David (FNIH) [T]" (b) (6) , "Anderson, James (NIH/OD) [E]" < (b) (6) "Burklow, John (NIH/OD) [E]" (b) (6) , "Carluccio, Dana" (b) (6) >, "Castillejos, Carlos" < (b) (6) , "Culp, Michelle (NIH/OD) [E]" (b) (6) >, FNIH Central Account (b) (6) , "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) (b) (6) "Hallett, Adrienne (NIH/OD) [E]" (b) (6) (b) (6) , "Lumsden, Joanne (NIH/NCATS) [C]" (b) (6)) (6) , "Myles, Renate (NIH/OD) [E]" (b) (6) , "Wolinetz, Carrie (NIH/OD) [E]" (b) (6)) (6) , "Burklow, John (NIH/OD) [E]" < (b) (6) "Hallett, Adrienne (NIH/OD) [E]" (b) (6) , "Meltzer, Abbey (FNIH) [T]" (b) (6) >, "Myles, Renate (NIH/OD) [E]" (b) (6) , "Wolinetz, Carrie (NIH/OD) [E]" (b) (6) , "Esser, Mark" (b) (6) (b) (6)

Cc: "Austin, Sarah (NIH/NIAID) [E]" < (b) (6) "Barasch, Kimberly (NIH/NIAID) [C]" (b) (6) >, "Bell, Julie" (b) (6) , "Burrus-Shaw, Cyndi (NIH/OD) [E]" < (b) (6) , "Carver, Trea (NIH) [C]" < (b) (6) , "Caulfied, Anita" (b) (6) >, "Coan, Amanda" (b) (6) >, "Conrad, Patricia (NIH/NIAID) [E]" (b) (6) , "Dimishkov, Roxanne (NIH/NHLBI) [C]" (b) (6) , "Edl, Susan" < (b) (6) , "Fuhrer, Nicole" (b) (6) >, "Giorgi, Sara" (b) (6) >, "Hoban, Michelle" (b) (6) >, "Hoffstetter, Renata (FNIH) [T]" (b) (6) Iberdemaj, Vaide" (b) (6) (6) , "Jenkins, Christine S." (b) (6) (b) (6) "Krack, Kimberly" <kimberly>, "a. (b) (6) (b) (6) , "Lagos, Enrique (NIH/NCATS) [E]" (b) (6) , "Lever, Susan" < (b) (6) , "Magbie-Robinson, Kim (NIH/OD) [C]" (b) (6) >, "Martin, Melisa" < (b) (6) , "McManus, Ayanna (NIH/OD) [E]" (b) (6) >, "Melencio, Cheryl (FNIH) [T]" < (b) (6) , "Minnich, Beth" (b) (6) , "Perala, Mie" (b) (6) , "Protasiewicz, Ann" <ann. (b) (6) , "Riccobene, Kim" < (b) (6) , "Riggin, Mary" < (b) (6) , "Ripley, Nadege" (b) (6) >, "Schuster, Donna" < (b) (6) , "Sepulveda, Dorina (FNIH) [T]" (b) (6) >, "Simon, Dina (NIH/OD) [C]" (b) (6) >, "Suhana, Tina (NIH/VRC) [E]" < (b) (6) , "Thomas, Ashley (FDA/CDER)" (b) (6) , "Wood, Gretchen (NIH/OD) [E]" (b) (6) , "Burrus-Shaw, Cyndi (NIH/OD) [E]" (b) (6) (b) (6) "Carver, Trea (NIH) [C]" (b) (6) >, "Hughes, Karen (NIH/OD) [E]" (b) (6)) , "Lagos, Enrique (NIH/NCATS) [E]" < (b) (6) , "Magbie-Robinson, Kim (NIH/OD) [C]" (b) (6) , "Melencio, Cheryl (FNIH) [T]" (b) (6) , "Simon, Dina (NIH/OD) [C]" (b) (6) , "Togashi, Mieko (NIH/NCI) [E]" (b) (6) , "Underwood, Nancy" < (b) (6) >, "Zottoli, Jessica" (b) (6) >, " (b) (6) , "Ellis, Carol" < (b) (6)

Subject: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, January 14, 2021

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Thursday, January 14 from 10:30 AM – Noon Eastern U.S. Time.** The minutes from the December 16 Executive Committee/Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 6/21/2020 5:49:11 PM

To: Draghia-Akli, Ruxandra [(b) (6) Garner, Carl [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eisner, Mark [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Gottesdiener, Keith (b) (6)) (6) Hughes, Eric (b) (6) (b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Wung, Peter /US [(b) (6) Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Chen, Helen Q. [(b) (6)

Subject: Request for the ACTIV Therapeutics-Clinical WG from the CTC WG

Dear ACTIV TX-Clinical WG members,

We have had a request from the Clinical Trial Capacity WG to assist in a survey they are conducting on trial innovations. We were hoping that each of you would be able to fill out the following online survey. There are just two required questions and two others that are optional.
https://forms.office.com/Pages/ResponsePage.aspx?id=eHW3FHOX1UKFByUcotwrBrylKqh49V5CqfAO1l8UUONUMFA1OE5TR1VFWEFGQUxQRFVDR0lXRDRRUC4u

Thanks in advance for your help with this. If you have any questions, feel free to contact myself or Karen Tountas (b) (6).

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/19/2020 2:23:05 AM
To: Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6) Keith Gottesdiener [(b) (6) Elliott Levy [(b) (6) Wung, Peter /US [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6) Salathin, Carla [(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account [(b) (6)

Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
Attachments: Therapeutic information request form-v9-clean.docx; ACTIV_Therapeutics Clinical Agent Prioritization Sub Group_19May2020 Meeting Guide.pdf
Location: https://fnih.zoom.us, (b) (6)

Start: 5/19/2020 5:00:00 PM
End: 5/19/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] ((b) (6) Rose Li Central Account

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

1. Slides with topics and agenda internal.
2. Updated Company RFI/Survey for final review.

Thanks,
Stacey

Join Zoom Meeting
https://fnih.zoom.us/ (b) (6) .

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Password: (b) (6)
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(b) (6) US (New York)
US (Germantown)

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Find your local number: https://fnih.zoom.us/ (b) (6) .

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

Sent: 11/6/2020 6:00:53 PM

To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell ((b) (6) [(b) (6) (b) (6) Cavaleri Marco [(b) (6) (b) (6) (b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) (b) (6) Tal Zaks [(b) (6)

CC: btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Dieffenbach, Carl (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94acc37973d346fa98dfe16cd1bf7013-cdieffenba]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Paul Gillard [(b) (6) François P Roman [(b) (6) Peter Dull [(b) (6) Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Martin, Stacey (CDC/DDID/NCEZID/DVBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffe35bbdbfbd495f97712313bedcaecc-ZMT0]; McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94d2e362b03243568fa31c3d23550095-xdf4]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; 'Wachtel, Jonathan' (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; (b) (6) ; (b) (6) Bethany Stokes [(b) (6) Kathleen Callahan [(b) (6) Molloy, Delia (DPH) [(b) (6) Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Filip Dubovsky [(b) (6)]; Michael Watson (x) [(b) (6)]; Jacqueline Miller [(b) (6)

Subject: Next ACTIV Vaccines Working Group meeting: Weds, 11 Nov

Dear Vaccines Working Group members,

As you may recall from the summer, we agreed to stop regular meetings of the Vaccines Working Group and reconvene as needed. Our next meeting will be Wednesday, 11 Nov, at 1pm ET (10am PT / 7pm CET).

We've been requested by ACTIV leadership to have a discussion about the priorities for vaccines in addition to the licensure studies. The Vaccines Clinical Trials Sub-Group has had previous meetings on the topics of evaluation in pregnant and pediatric populations, and is planning upcoming conversations about studying impact on transmission and evaluation in immunocompromised populations, as well as a discussion of the potential application of expanded access protocols.

At our next Working Group meeting, we would appreciate input on those and other potential priorities for discussion within the group. We are looking forward to your thoughts, and as always appreciate any questions or suggestions.

Best regards,

Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; david.j. (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] [(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Rao, Srinivas [(b) (6) Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) (b) (6) (b) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Desrosiers, Betsy [(b) (6)]; Jansen, Kathrin [(b) (6) Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Gonzalez, Nina [(b) (6) Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hawk, Harrison [(b) (6) Mason, Stephen [Stephen. (b) (6) (b) (6)

Start: 9/9/2020 2:00:00 PM
End: 9/9/2020 3:00:00 PM

Recurrence: (none)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 6/8/2020 8:57:42 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: another member for ACTIV Clinical Trial Capacity Working Group

Hi Karen,

I hope you are well and had a great weekend!

I think FNIH has developed a process for obtaining permissions for future participants which includes asking via email after they've indicated participation with the POC – cc'ing your very own Cheryl to confirm and who's been super helpful.

Also cc'ing Renate and Lauren Brodd for awareness only. Lauren will be working closely with me and Renate, NIH OD to assist with keeping the NIH website for ACTIV up to date.

Thanks again,
Ashley

From: Tountas, Karen (FNIH) [T] < (b) (6)
Sent: Monday, June 8, 2020 4:40 PM
To: Parker, Ashley (NIH/OD) [E] < (b) (6)
Cc: Meltzer, Abbey (FNIH) [T] < (b) (6)
Subject: another member for ACTIV Clinical Trial Capacity Working Group

Hi Ashley,

I hope you had a nice weekend. Please note that the CT Capacity Working Group has a new member from AstraZeneca.

- Therese Takas
  Director, Clinical Operations
  AstraZeneca

Her email contact to obtain permission to list her on the NIH ACTIV website is therese.takas@astrazeneca.com

Many thanks!
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health
(b) (6) | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

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Sent: 3/4/2021 11:04:28 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Thompson, Katherine (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f2c78f864ae43558adb82dc6b9a4d71-thompsonkap]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Also, should we change Janet Woodcock's organization to FDA? We are also checking with HHS to determine if we change OWS to COVID-19 Vaccines/Therapeutics Operation.

From: Myles, Renate (NIH/OD) [E]
Sent: Thursday, March 4, 2021 3:23 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Thompson, Katherine (FNIH) [T] < (b) (6)
Cc: Freire, Maria (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Gonzalez, Nina < (b) (6) Appell, Evan < (b) (6) Wojtowicz, Emma (NIH/OD) [E] < (b) (6)
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Hi David:

We list the Executive Committee on the ACTIV page and can replace Andy with Rajev on the organization chart and this Executive Committee governance page. We don't actually list the leadership on the ACTIV page.

Cheryl: will you be coordinating as per usual to see if these folks agree to be listed on the page and how they want to be listed?

Thanks,
Renate

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Thursday, March 4, 2021 2:54 PM
To: Wholley, David (FNIH) [T] (b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6) ; Thompson, Katherine (FNIH) [T] (b) (6)
Cc: Freire, Maria (FNIH) [T] (b) (6) Santos, Michael (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) Gonzalez, Nina (b) (6) Appell, Evan (b) (6)
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

I'm fine with that plan.

FC

From: Wholley, David (FNIH) [T] (b) (6) >
Sent: Thursday, March 4, 2021 1:08 PM
To: Myles, Renate (NIH/OD) [E] (b) (6) ; Meltzer, Abbey (FNIH) [T] (b) (6) >; Thompson, Katherine (FNIH) [T] (b) (6) >
Cc: Freire, Maria (FNIH) [T] (b) (6) Santos, Michael (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) Meltzer, Abbey (FNIH) [T] (b) (6) ; Collins, Francis (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Gonzalez, Nina (b) (6)) (6) >; Appell, Evan (b) (6))
Subject: FW: Notes from Wednesday's ACTIV Leadership Team Meeting

Can we please add Gary Dubin to the Vaccine WG rosters on the NIH and FNIH websites, and substitute Rajeev Venkayya for Andy Plump as the rep for Takeda to the ACTIV Leadership Team?

Francis, I am assuming this means Andy is also asking that Rajeev replace him on the Executive Committee. He's got a good background for PPPs—worked for four years on the WH biodefense team (wherefrom he knows Tony Fauci), is Andy's counterpart at Takeda as global head of their vaccines business, directed vaccines delivery at BMGF, and serves on the boards of SEPI and IAVI. I found him engaging and impressive, and am guessing Mike did too.
Thanks, David

From: Burke, Leslie (b) (6) **On Behalf Of** Venkayya, Rajeev
Sent: Thursday, March 4, 2021 12:03 PM
To: Santos, Michael (FNIH) [T] < (b) (6) >
Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) ; Venkayya, Rajeev < (b) (6)
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Mike,

I'm following up on Rajeev's behalf to let you know he would like to recommend his colleague **Gary Dubin, MD** (b) (6) for the Vaccines WG. Gary is the Head of our Global Medical Office, and leads the Takeda Vaccine Business Medical Affairs and Policy team. (b) (6) his Executive Assistant.

Gary will look forward to connecting!

Please don't hesitate to reach out with any questions.

Many thanks,

Leslie Burke
EA to Rajeev Venkayya, MD, President, Global Vaccine Business Unit
Vaccine Business Unit
Takeda Pharmaceutical Company Limited
Mail to: 40 Landsdowne Street, Cambridge, MA 02139, USA
Office location: 75 Sidney Street, Cambridge, MA 02139, USA
mobile: (
email: (b) (6) | ww.takedavaccines.com

From: Santos, Michael (FNIH) [T] (b) (6)
Sent: Monday, March 1, 2021 12:04 PM
To: Venkayya, Rajeev < (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] <c (b) (6) >; Burke, Leslie (b) (6)
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ:社外から送信されたメールです

Hi Rajeev,

It was great meeting and chatting. Your experience and perspectives are a great addition to the group.

As we discussed, attached are notes from the last few Vaccines WG meetings. The meetings are not under NDA, but our principle is that information shared during the meetings should only be used to advanced the shared objective of supporting COVID-19 vaccine development. So please feel free to share with the relevant people in your team, but not publicly.

If anyone is interested in joining the Vaccines Working Group, please let us know and we'll be happy to add them.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

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From: Venkayya, Rajeev (b) (6) >
Sent: Friday, February 19, 2021 11:21 PM
To: Santos, Michael (FNIH) [T] (b) (6)
Cc: Wholley, David (FNIH) [T] · Melencio, Cheryl (FNIH) [T] (b) (6) >; Burke, Leslie (b) (6)
Subject: Re: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Michael,

Thanks for the kind introduction and background. I know FNIH well and am looking forward to working with you. And yes, I'm sure we have many colleagues in common from BMGF!

An onboarding call would be helpful if it's not too much trouble. I'll ask Leslie to work with you to set that up. I look forward to that, and to meeting the ACTIV group!

Regards,

Rajeev

From: Santos, Michael (FNIH) [T] (b) (6)
Sent: Friday, February 19, 2021 4:59:22 PM
To: Venkayya, Rajeev (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6)
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ：社外から送信されたメールです

Dear Rajeev,

We heard from Andy Plump and Francis Collins that you are joining ACTIV. We're delighted to have you on the team.

The Foundation for the NIH manages ACTIV; David Wholley leads our work overall, I manage the Vaccines Working Group, and my counterparts manage the other Working Groups. If you are interested, we would be happy to have a call to provide context on ACTIV and the Vaccines Working Group and answer any questions that you have.

On a personal note, I was at BMGF for almost 6 years on the Discovery and HIV teams before I joined FNIH in late 2019. Although we missed overlapping there, I'm sure we know many people in common and I hope that we'll have the opportunity to connect sometime.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

---

From: Melencio, Cheryl (FNIH) [T] < (b) (6) **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Friday, February 19, 2021 4:07 PM
To: Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Bancel, Stephane (b) (6) ; Carter, Kara (b) (6) ; Cavaleri, Marco ; Cihlar, Tomas < ; Collins, Francis (NIH/OD) [E] (b) (6) ; Corey, Larry (b) (6) >; Culp, Michelle (NIH/OD) [E] < (b) (6) Victoria Davey < (b) (6) Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael (b) (6) >; Embry, Alan (NIH/NIAID) [E] (b) (6) >; Erbelding, Emily (NIH/NIAID) [E] Erck, Stan (b) (6) ; Fauci, Anthony (NIH/NIAID) [E] (b) (6) ; Freire, Maria (FNIH) [T] (b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) ; Gibbons, Gary (NIH/NHLBI) [E] <g (b) (6) >; Hudson, Thomas < (b) (6) ; James, Stephanie (FNIH) [T] (b) (6) ; Johnson, Robert (OS/ASPR/BARDA) < (b) (6) >; Kramer, Lynn (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Lepore, John < (b) (6) ; Marks, Peter (FDA/CBER) (b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) (b) (6) ; Meeker, David (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) ; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) >; Pandya, Hitesh (b) (6) >; Pangalos, Mene (b) (6) Pao, William < (b) (6) ; Parker, Ashley (NIH/OD) [E]

(b) (6) Paul, Steve (b) (6) Perlmutter, Roger (b) (6) (b) (6)
Plenge, Robert < (b) (6) Reed, John (b) (6) ; Reese, David < (b) (6) >;
Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] (b) (6) ; Skovronsky, Daniel
(b) (6) Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul
< (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) ; Talley, Michael
< (b) (6) Tsai, John (b) (6) Venkayya, Rajeev (b) (6) ;
Vessey, Rupert (b) (6) >; Virgin, Skip (b) (6) Wholley, David (FNIH) [T] < (b) (6)
Woodcock, Janet (FDA/OC) < (b) (6) Young, John (b) (6) ; Colvis,
Christine (NIH/NCATS) [E] (b) (6) Desrosiers, Betsy (b) (6) Eric
Hughes (b) (6) >; Jansen, Kathrin (b Kurilla, Michael (NIH/NCATS) [E]
(b) (6) Lowy, Douglas (NCI) <d (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) ;
Young, John (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) Margaret Anderson
(b) (6) >; Appell, Evan < (b) (6) Chen, Helen (b) (6)
Connelly, Sarah (b) (6) >; Dally, Nicolle (b) (6) >; Gonzalez, Nina
< (b) (6) Hawk, Harrison < (b) (6) Mendelson, Jesse (b) (6)
Menetski, Joseph (FNIH) [T] (b) (6) >; Nasr, Hana (b) (6) >; Santos, Michael (FNIH) [T]
(b) (6) >; Sorosa, Alex (b) (6) >; Stratton, Benjamin < (b) (6) Tolman,
Brett < (b) (6) Wachtel, Jonathan (b) (6) >; Wholley, David (FNIH) [T]
(b) (6) >; Plump, Andrew (b) (6)
Cc: Anderson, James (NIH/OD) [E] < (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) ;
Carluccio, Dana < (b) (6) Castillejos, Carlos (b) (6) ; FNIH Central Account
(b) (6) >; Lumsden, Joanne (NIH/NCATS) [C] (b) (6) >; Hallett, Adrienne
(NIH/OD) [E] (b) (6) 6) Meltzer, Abbey (FNIH) [T] (b) (6) Myles, Renate (NIH/OD) [E]
(b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6)
Subject: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Wednesday, February 17. Please let me know of any additional comments, questions, or suggestions regarding these notes.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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From: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]

Sent: 5/21/2020 3:34:20 PM

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; I (b) (6)) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) Tolman, Brett [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li

[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) (b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [(b) (6) (b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]

Subject: ACTIV Preclinical full working group

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; ACTIV Preclinical full working group; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Subgroup discussion of prediction of therapy resistance from emerging viral sequence data; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: ACTIV Preclinical full working group; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: https://fnih.zoom.us/ (b) (6)

Start: 1/13/2021 3:00:00 PM

End: 1/13/2021 4:00:00 PM

Show Time As: Tentative

Recurrence: Monthly
the second Wednesday of every 1 month(s) from 10:00 AM to 11:00 AM

Required Attendees: Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) ccolvis@mail.nih.gov; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; ken. (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello

(NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) (b) (6) (b) (6)

Optional Attendees: Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah; (b) (6) Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; (b) (6) Embry, Alan (NIH/NIAID) [E]; Lerner, Andrea (NIH/NIAID) [E]

Changing time for preclinical WG

Joe Menetski (he/him/his) is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
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Meeting ID: (b) (6)
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US (New York)
US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)
Meeting ID: (b) (6)
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Sent: 8/28/2020 12:48:24 PM
Subject: FW: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Attachments: 8.26 ACTIV Leadership Team Meeting 20200825 vFinal.pdf; 2020-07-29_ACTIV_Leadership_Team_Meeting_Summary final.pdf; 2020-08-14_Executive_Committee_Meeting_Summary vFinal.pdf

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From: Melencio, Cheryl (FNIH) [T] < (b) (6) **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, August 25, 2020 9:47 PM
To: Austin, Christopher (NIH/NCATS) [E] < (b) (6) Bancel, Stephane < (b) (6) Carter, Kara < (b) (6) Cavaleri, Marco < (b) (6) Cihlar, Tomas < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6) Corey, Larry < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) Dolsten, Mikael < (b) (6) Erbelding, Emily (NIH/NIAID) [E] < (b) (6) Erck, Stan < (b) (6) Fauci, Anthony (NIH/NIAID) [E] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) Hudson, Thomas < (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Johnson, Robert (OS/ASPR/BARDA) < (b) (6) Kramer, Lynn < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Lepore, John < (b) (6) Marks, Peter (FDA/CBER) < (b) (6) Marston, Hilary (NIH/NIAID) [E] < (b) (6) Mascola, John (NIH/VRC) [E] < (b) (6) Meeker, David < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) Pandya, Hitesh < (b) (6) Pangalos, Mene < (b) (6) Pao, William < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Paul, Steve < (b) (6) Perlmutter, Roger < (b) (6) Plenge, Robert < (b) (6) Plump, Andy < (b) (6) Rachel Ramoni < (b) (6) Rasi, Guido < (b) (6) Reed, John < (b) (6) Reese, David < (b) (6) Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Skovronsky, Daniel < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Stoffels, Paul < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Talley, Michael < (b) (6) Tsai, John < (b) (6) Vessey, Rupert < (b) (6) Virgin, Skip < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Woodcock, Janet (FDA/CDER) < (b) (6) Young, John < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy < (b) (6) Eric Hughes < (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Young, John < (b) (6)
Cc: Adam, Stacey (FNIH) [T] < (b) (6) Alvarez, Rosa < (b) (6) Anderson, Margaret < (b) (6) Chen, Helen < (b) (6) Elsaid, Olivia < (b) (6) Gonzalez, Nina < (b) (6) Hawk, Harrison < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Stratton, Benjamin < (b) (6) btolman < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Castillejos, Carlos < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) FNIH Central Account < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Hallett, Adrienne (NIH/OD) [E] < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Burklow, John (NIH/OD) [E]

< (b) (6) Gorman, Greta (FNIH) [T] < (b) (6) Hallett, Adrienne (NIH/OD) [E]
< (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E]
< (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Lucas Smalldon
< (b) (6) Villafana, Tonya < (b) (6) Brian Rosen
< (b) (6)

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Importance: High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]

Sent: 5/25/2020 7:43:44 PM

To: Vincent, Mike [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bascles, Lionel [(b) (6) Corey, Larry [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers , Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan (b) (6) Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]

CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Jintanat Ananworanich [(b) (6) Walker, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e577497e37b244168bd76c0b8827ca71-Robert.Walk]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; Hughes, Eric [(b) (6) Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6) Mueller-Reichenstein, Petra [petra. (b) (6) Quadros, Nora [(b) (6) m]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin (b) (6) (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05262020.pdf
Location: https://fnih.zoom.us/ (b) (6)

Start: 5/26/2020 1:00:00 PM
End: 5/26/2020 2:00:00 PM
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Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Vincent, Mike; Goff, David (NIH/NHLBI) [E]; Bascles, Lionel; Corey, Larry; Cohen, Myron; Davey, Victoria; Desrosiers , Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail
Optional Attendees: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Jintanat Ananworanich; Walker, Robert (OS/ASPR/BARDA); Mason, Robin (OS/ASPR/BARDA); Hughes, Eric; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (rebecca.katz@nih.gov); Zoe (NIH/NHLBI) Hill [C] ((b) (6) Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] (b) (6) 5) Carluccio, Dana; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Dear Colleagues, Attached is the Agenda for the Clinical Trial Capacity Working Group agenda. I am please to let you know that BARDA (Biomedical Advanced Research and Development Authority, U.S. Dept of Health and Human Services) will join the meeting to talk about their CRO relationships. With best regards, Karen

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May. We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen

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CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [(b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Garner, Carlos [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Minnich, Beth [bminnich@fredhutch.org]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin

[(b) (6) Tolman, Brett [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [(b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05192020.pdf
Location: https://zoom. (b) (6)

Start: 5/19/2020 1:00:00 PM
End: 5/19/2020 2:00:00 PM
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Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers , Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia
Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] ((b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] ((b) (6) Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding each topic! Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

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Scientific Program Manager
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